HEALTH TECHNOLOGY CASE STUDY 33

Technologies for Managing Urinary Incontinence

JULY 1985

This case study was performed as part of OTA's assessments:

Federal Policies and the Medical Devices Industry
and
Technology and Aging in America

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CONGRESS OF THE UNITED STATES
Office of Technology Assessment
Washington, D.C. 20510

J952-32

Recommended Citation:

Ouslander, Joseph, Kane, Robert, Vollmer, Shira, and Menezes, Melvyn, *Technologies for Managing Urinary Incontinence* (Health Technology Case Study 33), OTA-HCS-33, Washington, DC: U.S. Congress, Office of Technology Assessment, July 1985. This case study was performed as part of OTA's assessments of *Federal Policies and the Medical Devices Industry* and *Technology and Aging in America*.

Library of Congress Catalog Card Number 85-600554

For sale by the Superintendent of Documents
U.S. Government Printing Office, Washington, DC 20402

Preface

Technologies for Managing Urinary Incontinence is Case Study 33 in OTA's Health Technology Case Study Series. This case study has been prepared in connection with two OTA projects: *Federal Policies and the Medical Devices Industry and Technology and Aging in America*. The former project, conducted by the Health Program, was requested by the House Committee on Energy and Commerce and its Subcommittee on Health and the Environment and the Senate Committee on Finance, Subcommittee on Health. The latter project, conducted by the Biological Applications Program, was requested by the House Select Committee on Aging, and the Senate Special Committee on Aging. A listing of other case studies in the series is included at the end of this preface, and endorsed by the House Committee on Education and Labor.

OTA case studies are designed to fulfill two functions. The primary purpose is to provide OTA with specific information that can be used in forming general conclusions regarding broader policy issues. The first 19 cases in the Health Technology Case Study Series, for example, were conducted in conjunction with OTA's overall project on *The Implications of Cost-Effectiveness Analysis of Medical Technology*. By examining the 19 cases as a group and looking for common problems or strengths in the techniques of cost-effectiveness or cost-benefit analysis, OTA was able to better analyze the potential contribution that those techniques might make to the management of medical technology and health care costs and quality.

The second function of the case studies is to provide useful information on the specific technologies covered. The design and the funding levels of most of the case studies are such that they should be read primarily in the context of the associated overall OTA projects. Nevertheless, in many instances, the case studies do represent extensive reviews of the literature on the efficacy, safety, and costs of the specific technologies and as such can stand on their own as a useful contribution to the field.

Case studies are prepared in some instances because they have been specifically requested by congressional committees and in others because they have been selected through an extensive review process involving OTA staff and consultations with the congressional staffs, advisory panel to the associated overall project, the Health Program Advisory Committee, and other experts in various fields. Selection criteria were developed to ensure that case studies provide the following:

- examples of types of technologies by function (preventive, diagnostic, therapeutic, and rehabilitative);
- examples of types of technologies by physical nature (drugs, devices, and procedures);
- examples of technologies in different stages of development and diffusion (new, emerging, and established);
- examples from different areas of medicine (e.g., general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (e.g., cost);
- examples of technologies with associated high costs either because of high volume (for low-cost technologies) or high individual costs;
- examples that could provide information material relating to the broader policy and methodological issues being examined in the particular overall project; and
- examples with sufficient scientific literature.

Case studies are either prepared by OTA staff, commissioned by OTA and performed under contract by experts (generally in academia), or written by OTA staff on the basis of contractors' papers.

OTA subjects each case study to an extensive review process. Initial drafts of cases are reviewed by OTA staff and by members of the advisory panel to the associated project. For commissioned cases, comments are provided to authors, along with OTA's suggestions for revisions. Subsequent drafts are sent by OTA to numerous experts for review and comment. Each case is seen by at least 30 reviewers, and sometimes by 80 or more outside reviewers. These individuals may be from relevant Government agencies, professional societies, consumer and public interest groups, medical practice, and academic medicine. Academicians such as economists, sociologists, decision analysts, biologists, and so forth, as appropriate, also review the cases.

Although cases are not statements of official OTA position, the review process is designed to satisfy OTA's concern with each case study's scientific quality and objectivity. During the various stages of the review and revision process, therefore, OTA encourages, and to the extent possible requires, authors to present balanced information and recognize divergent points of view.

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[b]Original publication numbers appear in parentheses.

[c]The first 17 cases in the series were 17 separately issued cases in *Background Paper #2: Case Studies of Medical Technologies*, prepared in conjunction with OTA's August 1980 report *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

[d]Background Paper #3 to *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

[e]Background Paper #5 to *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

[f]Background Paper #1 to OTA's May 1982 report *Technology and Handicapped People*.

[g]Background Paper #2 to *Technology and Handicapped People*.

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NOTE: OTA appreciates and is grateful for the valuable assistance and thoughtful critiques provided by the advisory panel members. The views expressed in this OTA report, however, are the sole responsibility of the Office of Technology Assessment.

Contents

	Page
CHAPTER 1: INTRODUCTION AND SUMMARY	3
The Problem of Urinary Incontinence	3
Prevalence	4
Types and Causes	4
Treatments for Urinary Incontinence	4
Effectiveness	5
Costs	5
The Manufacturers of Incontinence Products	6
Industry Structure	6
Marketing	6
Policy Implications	7
Information	7
Research	7
Payment	8
Organization of This Case Study	8
CHAPTER 2: THE PROBLEM OF URINARY INCONTINENCE	11
Prevalence of Incontinence	11
Types and Causes of Incontinence	15
Treatments for Urinary Incontinence	17
CHAPTER 3: EFFECTIVENESS AND SAFETY OF DEVICES AND OTHER TREATMENTS	25
Artificial Sphincters	25
Electrical Stimulation	29
Catheters	32
Bedpads and Undergarments	33
Surgery	34
Drug Treatment	34
Training Procedures	36
CHAPTER 4: THE COSTS AND FINANCING OF INCONTINENCE	45
Costs of Incontinence	45
Payment for Urinary Incontinence	47
APPENDIX A.—INCONTINENCE PRODUCT MANUFACTURERS: CHARACTERISTICS AND OPINIONS	51
APPENDIX B.—INCONTINENCE PRODUCT MANUFACTURERS	54
APPENDIX C.—INCONTINENCE PRODUCT QUESTIONNAIRE	55
APPENDIX D.—ARTIFICIAL SPHINCTERS: A CASE STUDY	61
APPENDIX E.—GLOSSARY OF TERMS	63
APPENDIX F.—ACKNOWLEDGMENTS AND HEALTH PROGRAM ADVISORY COMMITTEE	64
REFERENCES	69

Contents—continued

List of Tables

Table No.	*Page*
2-1. Prevalence of Incontinence	12
2-2. Types of Incontinence	16
2-3. Treatments for Urinary Incontinence	19
3-1. Sphincter Devices	26
3-2. Electrical Stimulators	30
3-3. Bedpads and Undergarments	35
3-4. Drugs in Incontinence Treatment	37
4-1. Estimated Relative Costs of Treatments for Incontinence	46

List of Figures

Figure No.	*Page*
2-1. Treatment Options for Urinary Incontinence	18

1.
Introduction and Summary

1. Introduction and Summary

This case study describes medical devices and other technologies used to manage urinary incontinence and reports on the firms that produce such devices. This subject was selected for detailed study as part of two larger OTA assessments of Federal policies and the medical devices industry and technology and aging in America. Urinary incontinence represents a medical problem that is prevalent among the elderly and has enormous consequences for medical care costs. It is also an area in which medical devices with widely varied characteristics are used to manage or cure the underlying conditions. These devices complement other approaches to the management of urinary incontinence, and an analysis of the respective roles of alternative strategies is useful. Although the case study emphasizes mechanical devices over more conventional and widely used treatments for incontinence, such as drugs, surgery, and bladder-training procedures, these other treatments are also discussed. Evidence on the effectiveness and costs of alternative treatments is presented, and implications for public policy are discussed.

THE PROBLEM OF URINARY INCONTINENCE

Urinary incontinence is an embarrassing, potentially disabling, and costly health problem. Defined as an involuntary loss of urine sufficient in quantity and/or frequency to be a social or health problem, this condition disrupts the lives of 5 to 10 million Americans, their families, friends, and caregivers. The severity of incontinence ranges from occasional dribbling to total loss of control over excretory functions with incontinence of both urine and stool. It has adverse effects on physical health, psychological well-being, social functioning, and the cost of health care. When inadequately or inappropriately managed, it can lead to skin breakdown and recurrent urinary infections. Incontinent individuals often withdraw from their usual social activities and may subsequently become isolated and depressed. Because it is difficult for affected individuals and their families to manage at home, incontinence often plays a pivotal role in an individual's decision to enter a long-term care institution. The costs of labor, laundry, and supplies used to manage incontinence and its complications contribute to the growing costs of nursing-home care (111). Despite the availability of many effective forms of treatment, incontinent persons are rarely evaluated thoroughly to determine the precise causes of the condition and are therefore often not treated optimally (112).

This deficiency in the care of incontinent persons results from a number of factors, including:

1. lack of knowledge on the part of health-care professionals about the underlying causes of incontinence, appropriate methods of diagnostic evaluation, and treatment options available (in some instances, health-care professionals even consider incontinence a normal condition in elderly patients and therefore do not evaluate or attempt to treat it);
2. reluctance on the part of affected individuals to discuss the problem with a health-care professional because of embarrassment and the misconception that it cannot be treated; and
3. the relatively small number of experts (urologists, gynecologists, neurologists, geriatricians, nurse clinicians, etc.) available to treat these patients, train other health-care professionals, and carry out well-designed research on the management of this important health problem.

Prevalence

Because little accurate data on the extent of urinary incontinence have been consistently maintained, estimates of its prevalence and change over time are difficult to make. Current data indicate that risk of urinary incontinence is strongly associated with age. From 10 to 20 percent of the community-dwelling elderly, whose median age is 72, are incontinent to some degree. But approximately 50 percent of all elderly persons in nursing homes, whose median age is 83, are incontinent. Not only is the prevalence much greater among the latter group, but the type of incontinence is also likely to be more severe. Although these population subgroups are not directly comparable, the differences in prevalence indicate the increased risk of urinary incontinence for persons 65 to 74 and 85 and over (85,178). Risk of institutionalization is increased because of urinary incontinence. Thus, the very old (persons 85 and over) are most likely to suffer from incontinence and to be at risk of institutionalization.

The effects of these age-related differences will become more relevant as the aging of the U.S. population continues, especially within the older population itself. During the past decade, the elderly U.S. population has experienced a new era of increased longevity. In contrast to earlier periods when life expectancy advances were concentrated in infants and the very young, life expectancy at age 65 and 75 has markedly increased during the last 12 years (158). As a result, the very old are the fastest growing segment of the population. They currently comprise 9 percent (2.4 million persons) of the total older population, but are projected to increase to approximately 15 percent (5.1 million persons) by 2000. If present trends continue, this growth in the very old population will be accompanied by notable increases in the numbers and proportions of older persons with some degree of urinary incontinence and a higher risk of institutionalization. Technologies that can prevent, treat, cure, manage, or reduce the severity of urinary incontinence will help to lessen its prevalence, minimize its impact, delay its onset, and reduce the likelihood of institutionalization among the elderly.

Types and Causes

Incontinence can be classified into several types, which have clinical and therapeutic differences. *Acute incontinence* refers to the sudden onset of episodes of involuntary loss of urine, it is usually associated with an acute illness or environmental factors that impair the mental or physical ability of the patient to reach a toilet or toilet substitute in time.

Established or *persistent incontinence* (i.e., repeated episodes of involuntary loss of urine not associated with an acute condition) can be divided into four types. *Stress incontinence* implies leakage of urine, either in small or large amounts, as intra-abdominal pressure increases. *Urge incontinence* involves leakage of varying amounts of urine because of the inability to delay voiding long enough to reach a toilet or toilet substitute; it can be caused by a variety of genitourinary and neurologic disorders. *Overflow incontinence* is caused by anatomic obstruction to bladder emptying and/or inability of the bladder to contract, with subsequent leakage of small amounts of urine. *Functional incontinence* occurs in those individuals who have chronic impairments of either mobility or mental function, are unable to toilet themselves independently and do not have sufficient help with this task, or who, because of psychological disturbances, are unwilling to maintain continence.

TREATMENTS FOR URINARY INCONTINENCE

The most appropriate treatment for an individual patient with urinary incontinence depends on a thorough evaluation of all relevant factors (genitourinary, neurological, psychological, and environmental) that could cause or contribute to the condition. Most treatments discussed in this case study (e.g., sphincters, electrical stimulators, drugs, training procedures, and surgery) are appli-

cable for a specific type or types of incontinence and are attempts to cure the incontinence. Thus, a diagnostic evaluation to identify specific conditions is critical to the appropriate use of these treatments. Some of the treatments are nonspecific (e.g., bedpads, undergarments, and, in certain situations, catheters) and are palliative rather than curative; they should not be used exclusively until a diagnostic evaluation has excluded treatable conditions.

Devices for incontinence can be divided into those that attempt to prevent or delay urine flow and those that collect urine before or after it leaves the bladder. Devices such as the *pessary*, a donut-shaped piece of inert material inserted into the vagina to support the bladder outlet in women with stress incontinence, and the *external penile clamp* are used relatively infrequently at the present time. Newer techniques such as the *artificial sphincter*, which is an inflatable cuff surgically implanted around the urethra, and *electrical stimulators*, which contract muscles of the pelvic floor in stress incontinence and inhibit bladder contraction in urge incontinence, have been used increasingly over the last 10 to 15 years (124).

Catheters are commonly used to manage incontinence, despite the well-known risks (e.g., infection) associated with their use (166). Probably the most actively marketed products used to manage incontinence are *undergarments* and *bedpads*. In general, these products are designed with a layer of highly absorbent material sandwiched between layers designed to keep the patient and the bed or clothing dry. A wide variety of techniques, which we have labeled *training procedures*, have also been described in the management of incontinence. We have categorized these training procedures into five basic techniques: pelvic floor (Kegel) exercises, biofeedback, bladder retraining, habit training, and behavioral modification.

Effectiveness

Few studies have systematically examined the efficacy, safety, and long-term cost effectiveness of the various treatments for urinary incontinence. Most published studies are reports of case series. The relative efficacy of various treatments has rarely been examined.

Costs

Similarly, few studies have systematically examined the costs of incontinence. A small number of reports have considered various components of the cost, such as the added costs of labor or supplies used to manage incontinence in long-term care institutions (111). It has been estimated that $8 billion is spent on incontinence in this country, and urinary incontinence accounts for one-third of costs of geriatric wards, but the basis of these estimates has not been described (20). The costs of incontinence go far beyond economic considerations: withdrawal from social activities, psychological distress, burden on family and caregivers, and the subsequent predisposition to institutionalization are all important potential effects of incontinence that are difficult to quantify.

One report has examined the overall costs of incontinence in nursing homes in this country. If only "first-order" costs are considered (i.e., the costs of managing incontinence without the costs of any complicating conditions), incontinence adds between $3 and $11 to the daily costs of caring for a nursing home patient (111). The range of costs is accounted for by differing costs of various techniques of management. Of the three components of these costs (labor, laundry, and supplies), the labor involved in managing the incontinent patient was the major contributor.

If one assumes that there are approximately 600,000 nursing home patients with some degree of urinary incontinence and that in three-quarters of these patients the incontinence is sufficiently severe that catheters or other specific management techniques are used, the yearly costs of incontinence in U.S. nursing homes can be estimated at between $0.5 and $1.5 billion (first-order costs only). This cost range represents between 3 and 8 percent of the total expenditure on nursing home care in this country. The costs of incontinence in the community are much more difficult to estimate. No studies have addressed these costs in any detail.

Loss of productivity in those individuals afflicted with incontinence and in those caring for the incontinent patient could be substantial. Incontinence can place physical, psychological, and

economic burdens on patients and caregivers, costs that are difficult to estimate. And as mentioned before, incontinence is often cited as a major factor in the decision to institutionalize a dependent person.

The potential cost effectiveness of evaluation and specific treatment for incontinence has never been systematically addressed. Although the proportion of incontinent patients that can be completely cured is unknown, many can clearly benefit from an evaluation that identifies treatable conditions; in some instances, treatment would lead to substantial amelioration of the incontinence. Some experts estimate that one-third of incontinent patients can be completely cured and most others kept dry and comfortable with appropriate management (174).

THE MANUFACTURERS OF INCONTINENCE PRODUCTS

The manufacturers of urinary incontinence products are a heterogeneous assortment, ranging from very large, diversified firms to very small ones. The products, too, vary considerably. Some are designed for broad consumer use; others for very discrete types of incontinence. The latter may have a high unit cost and require surgical implantation. Any effort to describe "the incontinence products industry" must recognize this diversity. To facilitate systematic collection of data from manufacturers, a questionnaire was designed and sent to 38 companies who had agreed to respond; 21 companies replied. (See app. C.)

Industry Structure

At least 48 companies are involved in the manufacture of one or more incontinence products. These companies vary dramatically in their size, the number of products manufactured, and other corporate characteristics. In many cases, it is virtually impossible to isolate the incontinence products component of a much larger corporation.

Marketing

Companies have primarily marketed incontinence products as medical devices rather than as consumer products, even those products with the characteristics of consumer goods (e.g., incontinence pads).

Manufacturers distribute them through various distributors and dealers or directly to users; 85 percent of those companies responding to a survey conducted by the authors use distributors and/or dealers to reach the users. Most of the manufacturers' promotional efforts have been directed toward physicians and others in the medical field, but the recent entry of two large paper-products firms into the disposable incontinence product market may herald a new marketing strategy directed toward the consumer.

An active advertising campaign designed to destigmatize incontinence can provide important information to consumers. But it can also potentially mislead the public. Because the emphasis is on encouraging the use of an undergarment, the consumer may be led to believe that this is the appropriate first line of treatment. The importance of careful evaluation to search for remediable conditions is not likely to be stressed, nor will other techniques for managing the problem be suggested.

The incontinence-products industry is extremely competitive, and price is one of the important mechanisms used by some companies to capture an increased share of the market. Except for services delivered as part of an acute hospitalization, Medicare coverage for incontinence products is quite limited. Coverage for urinary incontinence products under Medicaid varies from State to State.

POLICY IMPLICATIONS

As a great source of health and social cost, the problem of urinary incontinence raises important issues for public policy. With regard to the various urine-collection pads, pants, and sheets, a number of competitive products are available, all of which can greatly facilitate the management of the incontinent patient. The difficulty seems to lie in both patients' and providers' awareness of these and other alternative treatments.

Information

Both individuals with urinary incontinence and health professionals lack information on the variety of products and treatments available. To date, there has been very little education through either formal mechanisms or advertising to broaden awareness of possible options. The entry into the disposable pad market of a second major firm may make direct advertising to the public more extensive.

The Government could do a great deal to destigmatize this socially unacceptable problem. Private merchandising could also influence consumer attitudes. Once advertising taboos are broken, the pattern of active advertising across the media, observed earlier with such previously "undiscussed" products as sanitary pads, will likely be repeated for incontinence products.

Health professionals should know more about the management of incontinence than does the lay public. At present, there is no guarantee that this is the case. Beyond a few specialists in urology and geriatrics, few physicians have been formally instructed in the diagnosis, treatment, and management of incontinence. The need for better medical education about incontinence was recently noted in the report on geriatrics and medical education by the Association of American Medical Colleges (5). Professional education could be expanded to include more than management. Physicians could be taught to appreciate the potential for successful treatment and know-how to evaluate patients with incontinence. Government support for training, educational materials, and the like might improve the likelihood that physicians would be educated about the range of incontinence products.

Research

The state of knowledge in the field is rudimentary for so prevalent a health problem Well-designed randomized clinical trials to test the efficacy of alternative treatment approaches have not been conducted. Most studies to date have weak designs; many have no control groups, despite the frequent observation of placebo effects. Before such controlled trials are carried out, however, more precise classification of incontinent patients and rigorously defined outcome measures need to be developed. Practical research is similarly needed. Better techniques for inexpensive assessments are necessary if more patients are to be properly evaluated. Diagnostic tests that are simple to perform and could be carried out at a patient's bedside or in an office setting would greatly increase the chances for better clinical evaluations and subsequent management.

Within the Government, the appropriate focus of responsibility for the necessary research support is unclear. The National Institutes of Health, specifically the National Institute on Aging, has evidenced interest in incontinence research, but has not yet organized clinical trials of therapeutic modalities. The National Center for Health Services Research has sponsored limited work in this area and could potentially do more.

Specific attention needs to be directed to the question of what types of interventions are effective with different types of patients. For example, many incontinent nursing home patients are cognitively impaired and limited in mobility. Surgical approaches, drug treatment, and bladder retraining (as opposed to habit training) are less likely to be productive in this patient population. A clinical classification of incontinence corresponding to the likelihood of effective intervention could be used as a framework for assessing the utility of new approaches.

Reporting the consequences of incontinence has not been systematic. The Food and Drug Administration requires records of adverse reactions

25-314 O - 85 - 2

from drug treatments for incontinence, but no agency organizes the collection of information on the complications of untreated or undertreated incontinence. This type of data might be collected through clinical studies sponsored by the National Institutes of Health, or it could fall under the purview of the Centers for Disease Control.

Payment

Medicare covers the costs of diagnosis and evaluation of incontinence and, for institutionalized persons, incontinence supplies. However, supplies for noninstitutionalized persons are not covered by Medicare, except for patients' home health services, and they are only erratically reimbursed by Medicaid. There is no clear mandate to pay for these products. Some argue that, because incontinence is often cited as a major cause of nursing home admission, paying for management products for ambulatory patients might be a good investment. The debate is essentially the same one heard for various interventions designed to reduce nursing home use. Because we cannot identify those at high risk of nursing home admission, there is some danger that subsidizing a large number of incontinent persons would prevent few admissions; the cost to third-party payers such as Medicare and Medicaid is likely to be additive rather than substitutive.

A new Medicaid reimbursement system for nursing home care currently under development reflects the variation in the costs of such care. Several States have developed case-mix reimbursement mechanisms that acknowledge the increased costs associated with incontinence. However, under such approaches, the emphasis is on the costs of caring for such patients rather than on encouraging treatment to improve their condition. As with all cost-reimbursement approaches, the worse a patient's condition, the greater is the reward to the caregiver. An experiment conducted by the National Center for Health Services Research is currently underway to test the effects of paying nursing homes an incentive to accept incontinent patients and a bonus if the institutions are able to improve the patients' functional condition (170).

The costs of incontinence are substantial. For many, the use of disposable incontinence products is essentially a convenience issue and the question of affordability is really one of willingness to spend. For others on a very limited budget, the convenience may be financially out of reach. These persons may be at greatest risk of nursing home placement because of limited resources.

ORGANIZATION OF THIS CASE STUDY

The remainder of this case study provides a background for the findings and conclusions summarized above, and is divided into three chapters. In chapter 2 the prevalence, types, and causes of incontinence and alternative treatment approaches are discussed. Chapter 3 contains a review of the evidence available on the safety and effectiveness of alternative treatments. Finally, chapter 4 gives an overview of the costs involved in evaluating and managing incontinence and its complications.

2.
The Problem of Urinary Incontinence

2.

The Problem of Urinary Incontinence

This chapter presents information on the problem of urinary incontinence, its prevalence in the U.S. population, and the array of modalities available to manage and treat the problem.

PREVALENCE OF INCONTINENCE

Several studies have examined the prevalence of urinary incontinence. Most of the recently published studies are summarized in table 2-1. They vary in sample population, definition of incontinence, and methods used to collect data. Estimates of incontinence prevalence range from less than 1 percent in young, community-dwelling persons to greater than 50 percent in elderly populations in long-term care institutions.

Despite the variability in study designs and estimates of prevalence, some general conclusions can be drawn from the table. Incontinence is most common among individuals over age 65. Between 10 and 20 percent (2 to 4 million) of community-dwelling elderly have some degree of urinary incontinence. The prevalence increases to nearly 50 percent of those elderly in nursing homes (600,000 to 700,000 people). Although incontinence is less prevalent in younger populations, there are as many, if not more, younger persons with the condition. Despite the dearth of studies to establish the prevalence of incontinence in younger populations, the available data suggest that between 1 and 5 percent of those under 65 years have a persistent problem with urinary incontinence (between 2 and 10 million people). These numbers are probably underestimates, because individuals often deny this problem. Moreover, these numbers reflect only those persons affected at any one time: incontinence is a transient phenomenon in up to one-third of affected individuals (178).

The severity of incontinence varies considerably. The frequency and amount of urinary leakage are often important considerations in the management of the condition. In younger populations, incontinence involves either very small amounts of urinary leakage, as would be the case in young women with stress incontinence, or complete loss of control over excretory function, usually in younger individuals with neurologic disorders (e.g., spinal cord abnormalities, multiple sclerosis, or traumatic paraplegia). Many young children also persistently wet the bed (enuresis). In older persons, the severity of incontinence can vary from infrequent losses of drops of urine (as in stress incontinence) to occasional or frequent losses of large volumes of urine (as in urge incontinence), to continuous leakage of urine and associated stool incontinence (as in people with severe dementia or other neurologic disorders or surgical or traumatic injury to sphincter mechanisms). Although incontinence of both urine and stool is relatively uncommon in community-dwelling persons, close to 50 percent of those in nursing homes who are incontinent of urine also have episodes of fecal incontinence (67,112). Most patients with urinary and fecal incontinence (double incontinence) have severe impairments of mental and/or physical functioning. (The causes and treatment of fecal incontinence are beyond the scope of this study and are reviewed elsewhere (87).)

Other studies' findings on the prevalence of incontinence are germane. Health professionals commonly do not recognize the presence of incontinence or they fail to note it as a problem; consequently they do not pursue an evaluation (112). In addition, studies in Great Britain indicate that incontinent individuals often do not use services available to them, such as incontinence nurses, incontinence clinics, and laundry services (153,160,178,179). Thus, it appears that both health professionals and incontinent individuals tend to underreport and underevaluate incontinence and, as a result, probably manage the condition suboptimally.

Table 2-1.—Prevalence of Incontinence

Study	Population sample	Definition of incontinence	Method of data collection	Prevalence (percent)				Comments
				Age	Female	Male	Overall	
Studies done in the community:								
Yarnell and St. Leger (1979)	Random sample of community elderly (over age 65) drawn from two medical practices in South Wales (N = 388)	Was there any leakage of urine in the previous 12 months? If yes, what was the frequency and the time of day?	Personal interview and questionnaire given at home to subject, the next of kin or daily attendant		17	11	14	Urinary incontinence was related to a history of cerebrovascular disease, surgical procedures for prostatic conditions, or utero-vaginal prolapse One-third had incontinence for only a short time (less than 6 months) Nearly half those severely incontinent preferred to buy their own supplies of incontinence pads from their pharmacists rather than approach their general practitioner with the problem
Thomas, et al. (1980)	Individuals aged 5 and older from 12 general practices in Britain (N = 18,084)	Leakage of urine in inappropriate places and at inappropriate times, at least twice a month, regardless of quantity ("regular" incontinence) Considered "occasional" if less than twice a month	Postal questionnaire; parents responded for children under 15 Also interviewed 237 adults with regular incontinence (from one general practice)	Percentage with regular incontinence				Prevalence in females significantly higher than in males Prevalence of regular incontinence (as opposed to occasional incontinence) increased with increasing age after 35 Women who had more than four babies were most likely to report regular incontinence Less than one-third were getting health or social services for their incontinence Those with minimal incontinence generally saw no reason to seek help
				Age	Female	Male	All	
				5-14	5	7	6	
				15-64	9	2	5	
				65+	11	7	10	
				All	8	3	6	
				Percentage with any incontinence				
				Age	Female	Male	All	
				5-14	16	18	17	
				15-64	27	5	16	
				65+	25	15	21	
				All	25	9	17	
Feneley, et al. (1974)	One group practice in Great Britain, ages 5 and older (N = 7,000)	Involuntary excretion or leakage of urine in inappropriate places or at inappropriate times at least twice a month, regardless of quantity	Postal questionnaire; parents responded for children under 15	Age	Female	Male	All	81% has urinary incontinence only 20% had both urinary and stool incontinence 7% had stool incontinence only
				5-14	4	6	—	
				14-64	8	2	—	
				65+	14	6	—	
				All	8	3	5	
Vetter, Jones, and Victor (1981)	Community elderly (age 70+) from two general practices in South Wales (N = 1,280)	"Do you ever wet yourself if you are unable to get to the lavatory as soon as you need to or when you are asleep at night or if you cough or sneeze?" "How often does this happen?" "Is it a few drops or more?"	Structured interview		18	7	14	5% were severely incontinent (daily or more), 8% were less severely incontinent Prevalence increased with age Housebound and clinically anxious persons were more likely to be severely incontinent Incontinent subjects were more likely than continent subjects to be in contact with family members and less likely to be visited by friends One-third of incontinent individuals used no aids 36% of severely incontinent used some type of protection, whereas only 2% of less severely incontinent used any protection

Table 2-1.—Prevalence of Incontinence—Continued

Study	Population sample	Definition of incontinence	Method of data collection	Prevalence (percent)				Comments
				Age	Female	Male	Overall	
Wolin (1969)	Single nursing students in the U.S. who have never borne children (ages 17-25) (N = 4,211)	Stress incontinence = accidental passing of urine when intra-abdominal pressure increases, unrelated to voiding	Questionnaire; author discussed questions first					15% had some incontinence; 16% had daily incontinence Daily stress incontinence was related to urinary tract infection but not to age or regularity of sexual intercourse
Yarnell, et al. (1981)	Random sample of women older than 18 in South Wales (N = 1,060)	Loss of urine on the way to the toilet or with cough, laugh, sneeze, etc.	Personal interview by nurse using standardized questionnaire	Age 18-64 65-74 75+ All	Female 42 43 59 45	Male NA NA NA NA	All — — — —	Half those incontinent had stress symptoms alone; 15% had urge only, 35% had both In most, urinary loss was small and infrequent; 5% had to change clothes; 3% had to change clothes daily 3% felt incontinence interfered with social or domestic life, but only half sought medical advice
Studies done in both community and institutions:								
Thomas, et al. (1980)	All those over age 15 in the London boroughs short- and long-stay hospitals, psychiatric wards, day-care centers, ordinary and special schools, multiple sclerosis and spina bifida societies, and pad and laundry services (estimated total population of the study area = 359,000)	Involuntary excretion or leakage of urine in inappropriate places or at inappropriate times and at least twice monthly, regardless of quantity	Nurses and administrators of the institutions and community services filled out a questionnaire that asked for age, sex, address, and details about type of incontinence of people under their care	Age 15-64 65+ All	Female 0.2 3.0 1.1	Male 0.1 1.0 0.3	All 0.2 2.0 1.0	Considering only community residents, less than 1% of those under 65 and 1% of those over 65 were reported as incontinent
Feneley, et al. (1979)	All those over age 15 in Bristol who were under care of general practitioners, community nurses, hospital nurses, social and welfare services, or in old people's homes	Involuntary excretion or leakage of urine in inappropriate places or at inappropriate times and at least twice monthly, regardless of quantity	Incontinent patients were registered by general practitioners, community nurses, hospitals, old people's homes, and social and welfare services over the course of a year (details of process not specified)					Overall prevalence rate of 1% reported
Studies done in long-term care facilities:								
Ouslander, Kane, and Abrass (1982)	Patients 65+ in 7 U.S. nursing homes (4 proprietary, 3 nonprofit) (N = 842)	Any uncontrolled leakage of urine, regardless of amount or frequency	Incontinent patients identified by nurses and verified by interviews with patients and nurses		50	48	50	Of those who were incontinent, 34% had frequent incontinence (more than one episode per day); 28% had occasional incontinence; 10% had an external catheter; 28% had an in-dwelling catheter 64% had concomitant fecal incontinence 64% were incontinent on admission to the nursing home Most had severe impairments of cognitive function and/or mobility 45% had complications (skin irritation, urinary infections) Physicians noted or sought underlying cause of incontinence in less than 15%

Table 2-1.—Prevalence of Incontinence—Continued

Study	Population sample	Definition of incontinence	Method of data collection	Prevalence (percent)				Comments
				Age	Female	Male	Overall	
Jewett, et al. (1981)	New admissions to geriatric long-term care facility in Canada (N = 277)	Involuntary loss of urine that was a social or hygienic problem and was objectively demonstrated	Research nurse completed questionnaire		36	40	38	27% had mental disorders 30% could not give a history of their health status Urge incontinence most common
U.S. Department of Health, Education, and Welfare, Public Health Service (1975)	15 randomly selected patients in each of 288 nursing homes in Medicare/Medicaid program (N = 4,320) Total nursing home population = 283,914	Involuntary loss of urine or feces at least occasionally	Assessment form completed by nursing-home staff				55	6% had an in-dwelling or external device
Ouslander and Fowler (1983)	All patients in 90 VA nursing-home care units (N = 7,853)	Any uncontrolled leakage of urine regardless of amount or frequency	Survey questionnaire completed by nursing-home nurse supervisors				41	Of the incontinent patients: 96% were male; 70% were age 65 or older; 22% had an in-dwelling catheter; 37% had an external catheter (worn continuously); only 10% had less than one episode per day; 55% also had episodes of fecal incontinence

SOURCE: J. Ouslander and R. Kane, University of California at Los Angeles, 1984

TYPES AND CAUSES OF INCONTINENCE

Normal urination is a complex and dynamic process involving several anatomic structures and the coordination of numerous physiologic processes. In addition to the structures of the lower genitourinary tract (including the bladder itself, the urethra, the pelvic floor musculature, and, in men, the prostate gland), the brain, spinal cord, and peripheral nerves are all involved in the control of urination. Disruption in the normal function of any of these anatomic components can lead to problems with incontinence (174).

Maintaining continence depends on the normal physiologic function of the lower genitourinary tract, normal innervation and neurologic control over genitourinary function, mental awareness of the need to void, and the mental and physical capacities to reach a toilet or toilet substitute at the appropriate time. Thus, disorders of the genitourinary tract, neurologic disorders, psychological disturbances, and limitations in mobility or environmental factors (e.g., physical restraints or drugs) can all contribute to the development and persistence of incontinence.

The normal function of the lower genitourinary tract includes two basic processes: the storage of urine and its emptying. Problems that interfere with these functions can cause incontinence. In order to store urine, the bladder must accommodate increasing volumes of fluid under low pressure (i.e., it must be compliant). The sensation of bladder fullness must be perceived at an appropriate time, the bladder must have an adequate capacity (normally 300 to 600 ml, or about 1 pint), and the bladder must not contract involuntarily. In order to empty urine, the bladder must have the capability to contract voluntarily. There must be a coordinated lowering of resistance in the bladder outlet as the bladder contracts, and there can be no anatomic obstruction to urine flow. Any condition that impairs these normal functions of the lower genitourinary tract can cause incontinence.

Incontinence can be classified into several types (table 2-2). From a clinical and therapeutic viewpoint, there are important differences between causes of acute versus established (or persistent) incontinence. *Acute incontinence* refers to the sudden onset of episodes of involuntary loss of urine, which is usually associated with an acute illness or environmental factors that impair the mental or physical ability to reach a toilet or toilet substitute. This phenomenon is especially common in hospitalized elderly persons. Many elderly persons have the frequent and urgent need to void and often arrange their activities to be near a bathroom at the appropriate time. With the onset of an acute illness, incontinence can be precipitated by impairment of mobility (e.g., a hip fracture or cardiovascular decompensation) or confinement to a bed with bedrails and other restraints. Many elderly individuals also become confused with the onset of acute illness and admission to a hospital; their awareness of the need to void and their ability to find a toilet may therefore be impaired. Too often, elderly hospitalized persons who recognize the need to void but cannot obtain timely help in getting to the toilet are labeled incontinent by their nurses and physicians.

Other factors that can precipitate acute forms of incontinence include acute urinary tract infections with bladder inflammation, metabolic disorders (e.g., diabetes) that increase urine flow, fecal impaction which may either mechanically obstruct the normal emptying of the bladder or cause reflex involuntary contraction of the bladder, and a variety of drugs. Drugs that can precipitate incontinence include diuretics which increase urine flow, sedative, hypnotic, and antipsychotic agents which may diminish the mental awareness required for the maintenance of continence, and drugs that influence normal lower genitourinary functioning such as anticholinergic drugs (which inhibit the bladder from contracting) and certain antihypertensive agents (which decrease resistance in the bladder outlet) (14,122).

Established or *persistent incontinence* (i.e., repeated episodes of involuntary loss of urine not associated with an acute condition) can be divided into four types. *Stress incontinence* implies leakage of small, and sometimes large, amounts of

Table 2-2.—Types of Incontinence

Type	Definition	Causes	Population(s) affected
Acute:	Incontinence of sudden onset associated with an acute illness (and/or other factors) that subsides once the acute condition has been resolved or other factors have been removed	Acute illnesses associated with one or more of the following: (a) immobility and/or environmental factors that diminish the ability to get to and use a toilet; (b) impaired mental function that diminishes toileting ability; (c) fecal impaction. Acute urinary tract infections Drugs: (a) those that increase urine flow (e.g., diuretics); (b) those that inhibit bladder contractions and cause urinary retention and overflow (e.g., anticholinergics); (c) those that decrease mental awareness (e.g., sedatives, hypnotics) Metabolic—increased urine flow (polyuria) associated with poorly controlled diabetes	Elderly, usually in acute hospitals
Established:[a]			
Stress	Leakage of small amounts of urine with increases of intra-abdominal pressure (e.g., coughing, sneezing, laughing, exercise)	Weakened supporting tissue surrounding bladder outlet and urethra associated with: (a) lack of estrogen in postmenopausal women; (b) previous vaginal deliveries; (c) previous pelvic surgery (e.g., hysterectomy)	Women, especially those over age 40
Urge	Leakage of urine caused by inability to delay voiding long enough to reach the toilet after urge to void is felt	Neurological diseases such as stroke, dementia, Parkinsonism, multiple sclerosis, spinal cord diseases Genitourinary disorders such as unstable bladder ("detrusor instability"), bladder stones, diverticuli of urethra and bladder, atrophic urethritis, vaginitis (females), chronic cystitis, mild outflow obstruction (usually males)	Men and women of any age; most common in the elderly
Overflow	Leakage of small amounts of urine associated with obstruction to urine flow	Hypotonic or acontractile bladder associated with diabetic neuropathy; spinal cord injury; or drugs such as anticholinergics (which inhibit bladder contractions), smooth muscle relaxants, narcotics, and alcohol Anatomic obstruction associated with prostatic enlargement or urethral stricture	Older men with prostatic enlargement Diabetics
Functional	Inability or unwillingness to reach a toilet in time	Impaired mobility Impaired mental function Inaccessible toilets (or caregivers) Psychological disorders such as depression, psychosis, anger, or hostility	Elderly in acute hospitals and nursing homes and those with acute or severe psychiatric illness

[a]Incontinence is persistent and unrelated to an acute illness.

SOURCE: J. Ouslander and R. Kane, University of California, Los Angeles, 1984.

urine with increases in intra-abdominal pressure, such as would occur with exercise, straining, coughing, laughing, or sneezing. This type of incontinence usually occurs in women, especially those who have had multiple vaginal deliveries or pelvic surgery. It is generally related to weakened musculature of the pelvic floor and subsequent loss of resistance in the bladder outlet.

Urge incontinence involves leakage of varying amounts of urine (usually larger volumes than in stress incontinence) because of the inability to delay voiding long enough to reach a toilet or toilet substitute; it can be caused by a variety of genitourinary and neurologic disorders. This type of incontinence is often (but not always) associated with an unstable bladder (in the past referred to

by many names, including uninhibited neurogenic bladder, detrusor hyperreflexia, and detrusor instability). The final common pathway involves the involuntary contraction of the bladder at low or normal bladder volumes. It is the most common abnormality found in elderly incontinent individuals and is often responsive to drug treatment (22,32,81,174). (Drugs, however, have limitations in the management of incontinence, especially in the elderly.) People with urge incontinence generally empty their bladder completely, although some patients retain urine. (Urine is considered to be retained if more that 50 to 100 ml are left in the bladder after voiding). Any condition that causes local irritation in the lower genitourinary tract, such as chronic inflammation of the bladder or urethra, stones, tumors, or diverticula (outpocketings) of the bladder, can precipitate urge incontinence. Correcting the condition will often cure the incontinence. Neurologic disorders that impair central nervous system and spinal-cord control over bladder contraction (e.g., stroke, dementia, Parkinsonism, and multiple sclerosis) can also cause involuntary bladder contraction and urge incontinence. Nonetheless, a substantial proportion of individuals with urge incontinence have no demonstrable neurologic or genitourinary abnormality.

Overflow incontinence is caused by anatomic obstruction to bladder emptying and/or inability of the bladder to contract, with subsequent leakage of small amounts of urine. Most common in older men when benign prostatic hyperplasia anatomically obstructs urine flow, it can also be related to diabetic neuropathic bladders (which contract poorly), spinal cord injuries (which impair the innervation that causes bladder contraction), and a variety of drugs that impair bladder contraction. This type of incontinence usually requires either the surgical removal of the anatomic obstruction or chronic or intermittent catheter drainage to prevent recurrent urinary tract infections and renal failure, both of which can result from chronic urinary retention.

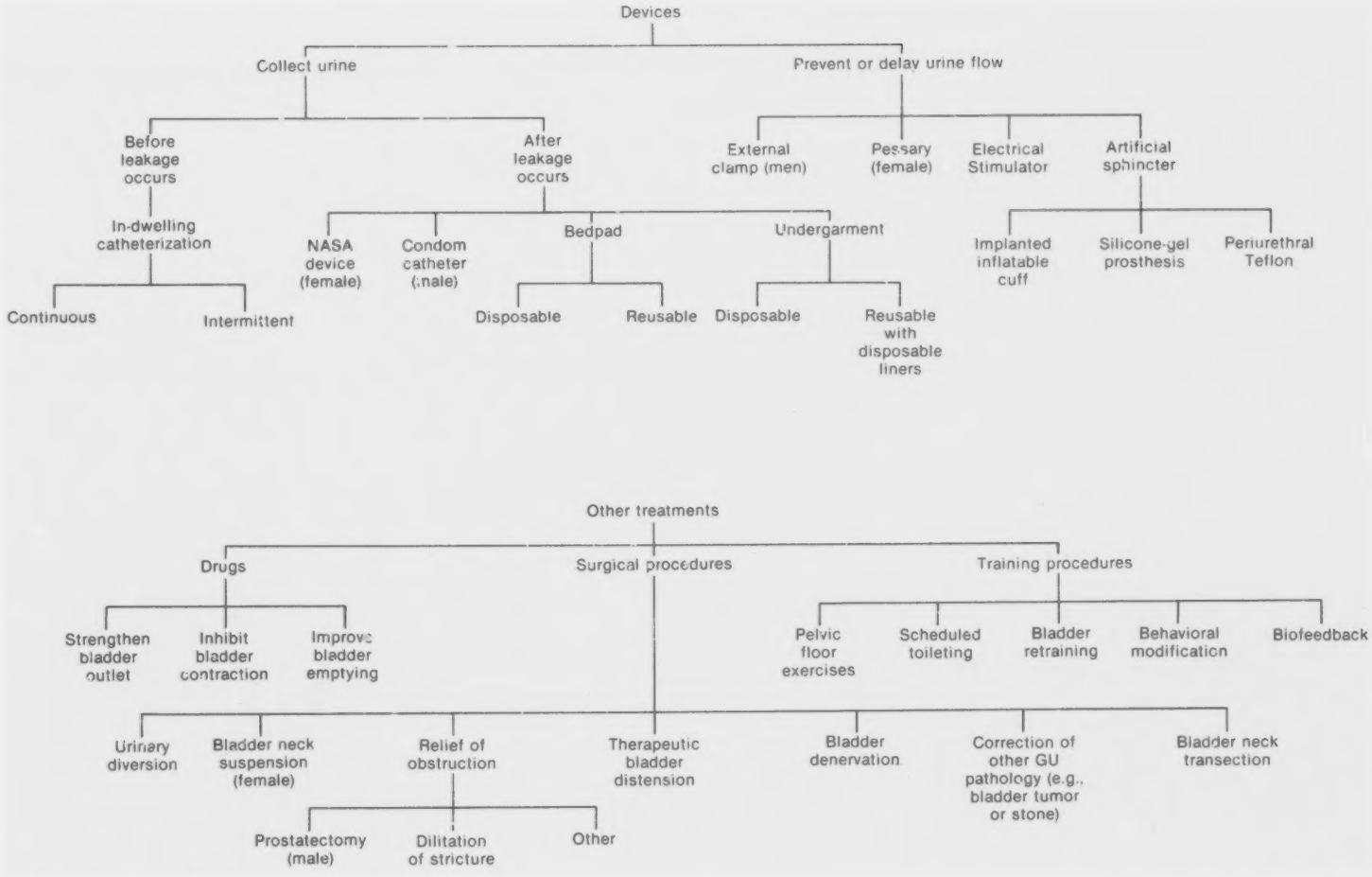
Functional incontinence occurs in individuals who have chronic impairments of either mobility or mental function, are unable to toilet themselves independently and do not have sufficient help with this task, or who, because of psychological disturbances, are unwilling to maintain continence. Functional incontinence can also be related to a variety of iatrogenic factors such as environmental barriers, inaccessible toilets and caregivers, and psychotropic medication.

TREATMENTS FOR URINARY INCONTINENCE

The most appropriate treatment for a patient with urinary incontinence depends on a thorough evaluation of all the relevant factors (genitourinary, neurological, psychological, and environmental) that could cause or contribute to the condition. Most treatments discussed in this case study (sphincters, electrical stimulators, drugs, training procedures, and surgery) are applicable to a specific type or types of incontinence and are attempts to cure the incontinence. Thus, a diagnostic evaluation to identify specific conditions is critical to the appropriate use of these treatments.

For the purposes of this case study, treatments for incontinence will be divided into devices and other treatments (fig. 2-1). Each type of treatment is briefly described in table 2-3. Devices for incontinence can be divided into those that attempt to prevent or delay urine flow and those that collect urine before or after it leaves the bladder. Devices such as the pessary, a donut-shaped piece of inert material inserted into the vagina to support the bladder outlet in women with stress incontinence, and the external penile clamp are used relatively infrequently at the present time. Newer techniques, such as the artificial sphincter, which is an inflatable cuff surgically implanted around the urethra, and electrical stimulators, which contract muscles of the pelvic floor in stress incontinence and inhibit bladder contraction in urge incontinence, have been used increasingly over the last 10 to 15 years. These devices, however, can be used effectively only in carefully selected pa-

Figure 2-1.—Treatment Options for Urinary Incontinence



SOURCE: J. Oslander and R. Kane, University of California at Los Angeles, 1984.

Table 2-3.—Treatments for Urinary Incontinence

Type of treatment	Examples	Mechanism	Uses
Devices: To collect urine before leakage occurs	Catheters	A flexible tube is placed directly in the bladder and drains urine into a collecting bag. Can be used continually or intermittently.	Inability to empty bladder (urinary retention) that cannot be corrected by surgical or drug treatment. (This may or may not be associated with overflow incontinence) Incontinence associated with healing skin lesions
To collect urine after leakage occurs	NASA (female) Condom catheters (male)	Outflow is trapped and drained into a collecting bag	Any type of incontinence
	Bedpads	Pad protects individual and mattress from contact with urine. These pads are disposable or reusable	Any type of incontinence, especially useful as adjunctive therapy with other treatments
Prevent or delay urine outflow	Artificial sphincters	Inflatable cuff is surgically implanted around urethra and inflated to prevent urine outflow	Incontinence associated with sphincter weakness (usually stress incontinence or postprostatectomy)
	Silicone-gel prosthesis	Silicone-gel is inserted to replace existing urethra	
	Periurethral Teflon	Teflon paste is injected into tissues surrounding urethra	
	Electrical stimulators	Device inserted into vagina; produces electric impulses that; (a) cause contraction of pelvic floor musculature; (b) inhibit bladder contractions	Incontinence associated with pelvic floor muscle weakness or bladder instability
	External clamp (male)	Penis is clamped to prevent urine flow	All types of male incontinence
	Pessary (female)	Device is inserted into vagina, supporting tissues below bladder and around urethra	Female incontinence associated with prolapsed pelvic structures (usually stress incontinence)
Other treatments: Surgical procedures	Bladder-neck suspension	Urethra and bladder neck are restored to a more normal intra-abdominal position	Female stress incontinence
	Prostatectomy (transurethral resection and suprapubic)	All obstructing portion of prostate is removed	Male overflow incontinence associated with anatomic obstruction
	Therapeutic bladder-neck transection	Bladder neck is surgically incised	Urge incontinence associated with bladder instability
	Selective bladder denervation (cystolysis)	Nerves to upper bladder are cut so that there is no muscle control of bladder dome, but sphincter mechanism is intact	Urge incontinence associated with bladder instability
	Therapeutic bladder distension	Bladder is distended under anesthesia for at least 2 hours to a pressure close to systolic blood pressure	Urge incontinence
	Correction of other genitourinary pathology (e.g., bladder tumor or stone)	Removal of irritative or obstructive factors	Urge incontinence associated with bladder instability Overflow incontinence associated with outflow obstruction

Table 2-3.—Treatments for Urinary Incontinence—Continued

Type of treatment	Examples	Mechanism	Uses
Drugs	Propantheline (Probanthine)	Diminish bladder contractions	Urge incontinence associated with bladder instability
	Imipramine (Tofranil)	Diminish bladder contractions	Urge incontinence associated with bladder instability
	Oxybutrin (Ditropan)	Diminish bladder contractions	Urge incontinence associated with bladder instability
	Flavoxate (Urispas)	Diminish bladder contractions	Urge incontinence associated with bladder instability
	Ephedrine (Sudafed)	Strengthen bladder outlet	Stress incontinence associated with sphincter weakness
	Phenylpropronolamine (Ornade)	Strengthen bladder outlet	Stress incontinence associated with sphincter weakness
	Estrogen (Premarin)	Increases supporting tissue around urethra	Stress incontinence
	Oral or topical Bethanechol (Urecholine)	Promotes bladder contraction	Overflow incontinence
Training procedures	Habit training	Caretaker determines individual's pattern of incontinence and gets him/her to toilet accordingly	Urge incontinence
	Bladder retraining	Caretaker establishes routine of fluid administration and toileting with progressive lengthening of toileting intervals to increase bladder capacity or re-initiate normal voiding	Urge incontinence After catheter use
	Pelvic floor exercises	Exercises to strengthen pelvic muscles	Overflow incontinence after overdistension injury incontinence
Stress	Biofeedback	With specialized equipment, patient is trained to inhibit bladder contractions or contract pelvic muscles	Mainly urge incontinence associated with bladder instability and stress incontinence associated with sphincter weakness
	Behavioral modification	Caretaker rewards incontinent individual for staying dry	Incontinence associated with underlying mental or emotional disorders; some forms of functional incontinence

SOURCE: J. Ouslander and R. Kane, University of California at Los Angeles, 1984

tients. In addition, only a limited number of health care professionals are knowledgeable in their use, and, therefore, only a few patients have been treated with them.

Catheters are commonly used to manage incontinence, despite the well-known risks associated with their use, such as urinary tract infections, penoscrotal abscess and epididymitis in men, sepsis, and death (91,98,120,144,166). Continuous in-dwelling catheterization is justified for the short-term management of incontinence in acutely ill individuals, in those undergoing genitourinary surgical procedures, in patients with skin breakdown needing protection from incontinent urine, and in patients with urinary retention that cannot be corrected surgically or pharmacologically or managed by intermittent catheterization. The technique is inappropriately used for the long-term management of a substantial proportion of institutionalized incontinent individuals (98,110). Intermittent catheterization can be used in carefully selected patients and may prevent the frequent infectious complications of continuous indwelling catheterization (92). External catheters (condom catheters) are most commonly used in elderly male incontinent patients; these devices require frequent changing by nursing staff or other caregivers and can result in serious complications (especially local skin irritations). Except for devices currently under development, only one female external-urine-collection device has been described in the literature (59).

Other treatments for urinary incontinence include surgical procedures, drugs, and a group of techniques that can be broadly labeled training procedures. As with the treatments mentioned above, surgical procedures are most useful if the nature of the underlying genitourinary pathology is understood. The most common surgical procedure used for incontinence is bladder neck suspension, which is used in women with stress incontinence (124). Other procedures, such as bladder denervation and bladder distention for the management of unstable bladder, are much less commonly used (44,114).

Drugs are most commonly used in the treatment of the unstable bladder, a common condition in patients with urge incontinence (14,109, 122). A variety of pharmacologic agents can inhibit bladder contraction and therefore are useful in the therapy for unstable bladder. Other drugs can strengthen the bladder outlet and can be used in the management of stress incontinence in females. Drugs used to treat stress incontinence are potentially toxic, especially in elderly women, and are generally less effective than surgical procedures (see table 2-3). Drug treatment to promote bladder contraction is used in the treatment of urinary retention with overflow incontinence.

Probably the most actively marketed products used to manage incontinence are undergarments and bedpads. In general, these products are designed with a layer of highly absorbent material sandwiched between layers designed to keep the patient and the bed or clothing dry (152). The majority of bedpads are disposable. Although several U.S. manufacturers offer reusable pads, the only specially designed reusable bedpad (the Kylie pad) has been developed and marketed in Australia, but is not yet available in the United States (24).

Several kinds of incontinence undergarments are currently marketed in this country (17,18). Some are completely disposable and resemble diapers; others have a launderable pant fitted with disposable liners. Although they are useful as adjuncts to other, more specific types of treatments and can help incontinent individuals remain dry, comfortable, and involved in social activities, these undergarments should be considered only as aids to management for incontinence until the patient has been evaluated and specific conditions and their treatments identified.

A wide variety of techniques, which we have labeled training procedures, have also been described in the management of incontinence (74, 171). Although the nomenclature for these procedures remains confusing (74), we have categorized the procedures into five basic techniques (fig. 2-1): pelvic floor (Kegel) exercises, biofeedback, bladder retraining, habit training, and behavioral modification. However, when one reads the literature on bladder training, especially that pertaining to nursing homes and other institutional settings, it becomes clear that most of these techniques have nothing to do with training the bladder; they generally involve training the staff to get the patient to the toilet on time (110).

3.
Effectiveness and Safety of Devices and Other Treatments

3. Effectiveness and Safety of Devices and Other Treatments

Few studies have systematically examined the efficacy and long-term cost effectiveness of the various treatments for urinary incontinence. Most published studies are reports of case series. The relative efficacy of various treatments has rarely been examined. In this chapter, we review in detail the published reports of the effectiveness of treatments for urinary incontinence, focusing especially on devices.

ARTIFICIAL SPHINCTERS

Several types of artificial sphincters have been developed and tested over the last two decades. The historical development of and the mechanisms by which these devices maintain continence are described in detail later in this case study. The most extensively tested types of sphincters are surgically implanted cuffs, which fit around the urethra and are controlled externally by the patient. Earlier models such as the AS 721, manufactured by American Medical Systems, required patients to both inflate and deflate the cuff. Later models, such as the AS 791 and AMS 800 TM, manufactured by American Medical Systems, require patients to deflate the cuff only when they desire to urinate; the cuff automatically inflates gradually after urination. These devices are implanted primarily for weakness or total dysfunction of the bladder outlet and urethral sphincter mechanisms. Patients with unstable bladders or urinary retention (secondary to anatomic obstruction of urine flow or an inadequately contracting bladder) are not appropriate candidates for an implantable sphincter and therefore must be excluded by preoperative urologic evaluation. In addition, candidates for artificial sphincters must be mentally and physically capable of managing the device and be motivated to do so (or have a caregiver available who will manipulate the device for them).

As shown in table 3-1, all published reports of artificial sphincters have been case series, not controlled clinical trials. Most commonly, artificial sphincters have been tested in males with incontinence following prostate surgery, in women with stress incontinence (many of whom have had previous unsuccessful surgical procedures to correct incontinence), and in children with spinal-cord abnormalities (myelomeningocele).

As the table demonstrates, artificial sphincters appear to improve or cure incontinence in 40 to 80 percent of patients. The duration of followup has ranged from a few months to longer than 3 years. Many patients developed complications from the procedure—primarily erosion of the sphincter cuff into the urethra. This was often a very serious and irreversible complication, occurring in up to one-quarter of treatment failures. Other complications included persistent infection and mechanical failure requiring removal and/or replacement of the device. A newer technique (primary deactivation), designed to minimize cuff erosion, involved leaving the cuff deflated for up to 3 months after the implantation to allow tissue healing.

In addition to the surgically implantable devices, other approaches to the artificial sphincter have been developed. A prosthesis made of a silicone gel has been implanted in patients with postprostatectomy incontinence. In the fewer than 200 cases reported, approximately 70 percent benefited from the prosthesis over a 1- to 2-year

Table 3-1.—Sphincter Devices

Sphincter device	Reference	Study design	Diagnosis	Criteria for improvement	Results	Comments
AS 721	Scott, Bradley, and Timm (1973)	Case Series (N = 5; 1 m, 4 fe) 10-day follow-up	4 neurologic disorder	Radiologic, office examination, urodynamics, tissue acceptance	100% success; all dry and void freely; voiding flow rates as good as or better than preoperative results; no discomfort after 10 days	
AS 721	Hald, Bystrom, and Alfthan (1975)	Case Series (N = 8; 6 m, 2 fe) 2-10 month follow-up	5 neurogenic bladder; 3 postsurgery	Continence	6 continent	
AS 721	Furlow (1976)	Case Series (N = 31; 29 m, 2 fe) Ages 22-78; 24-month follow-up	Most post-prostate surgery; 6 pelvic trauma	Continence	68% success	Major complications: 3 infections around prosthesis; 2 urethral erosions; 1 vesical neck erosion; 1 vesicorectal fistula; 1 defective cuff 9/26 continent patients required more than one revisit to maintain device function
AS 761	Balloon Sphincter Clinical Study Group (1977)	Case Series (N = 82)		Continence	57% successful initially; 2% improved; 41% failed	Failures from mechanical complications (e.g., valve failure); surgical failure (e.g., infection); patient selection (e.g., uninhibited bladder contractions)
AS 742	Balloon Sphincter Clinical Study Group (1978)	Case Series (N = 90)		Continence	68% success; 5% improved; 27% failed	Failures from surgical error (11); patient selection (3); mechanical failure (1)
AS 721 AS 742	Scott (1978)	Case series (N = 41)	Most post-prostate surgery; 10 pelvic fracture	Patient should not require bedpad; be continent with stress; and be able to urinate easily	Success rate = AS 721, 59%; AS 742, 92%; Overall, 78%	Success rate = 100% for incontinence resulting from urethral surgery or following radical prostatectomy Success rate = 50% for those with pelvic fracture causing disruption to membranous urethra 6/41 required removal of prosthesis because of surgical contamination and infection
742 A,B,C	Bruskewitz, et al. (1980)	Case Series comparing AS 742A with AS 742B or C Group I (N = 21; 19 m, 2 fe) Ages 7-83	Most post-prostate surgery; 2 female stress incontinence	Excellent = none or slight incontinence Improved = improvement but still moderate incontinence	14% excellent; 24% improved; 62% failure	Failures associated with cuff erosion (24%); infection (24%) patient's inability to operate the device and continued incontinence (24%)
		Group II (N = 17) Ages 9-81	Most post-prostate surgery; 15 had neurologic disorders; 2 pelvic trauma	Failure = unimproved	44% excellent; 6% improved; 50% failure	Failures associated with cuff erosion (33%); infection (11%); continued incontinence (6%) The higher balloon pressures in 742B and C were associated with increased rates of erosion
AS 742 A,B,C	Furlow (1981)	Case Series (N = 47; 41 m, 6 fe) Ages = 6-81; mean = 55	17 radical prostatectomy; 13 neurogenic bladder; 4 female stress incontinence	Continence	81% continent; 19% erosion	Device malfunction was not a significant cause of failure; half the failures were corrected by cuff replacement and deactivation
AMS 791/792	Scott, et al. (1981)	Case Series (N = 203; 129 m, 74 fe) Ages 5-84; 27-month follow-up	88 neurological disorders; 68 postoperative; 47 others	Failure = complications or persistent incontinence	85% success rate	Mechanical failures (26) mainly caused by cuff failure; 96 percent chance of success after first 6 months

Table 3-1.—Sphincter Devices—Continued

Sphincter device	Reference	Study design	Diagnosis	Criteria for improvement	Results	Comments
AS 742	Lindner, Kaufman, and Raz (1983)	Nonrandomized comparison of primary activation with delayed activation (N = 78; 76 m, 2 fe) Ages 6-83, mean = 60 Follow-up: Group I mean = 26.8 months; Group II mean = 9.2 months	Most post-prostate surgery	Dry Minimal stress incontinence Failure	Primary activation (N = 53): 40% dry; 15% minimal; 45% failed Delayed activation 58% dry; 7% minimal; 35% failed	Reasons for failure: Group I erosion, 19%; incontinent, 13%; infection, 11%; tube leaked, 2%; Group II erosion 24%; incontinent 12%
AMS 791/792	Reimenschneider and Moon (1983)	Case Series (N = 16) 2-12 month follow-up	Most post-prostate surgery	Patient dry between voiding; residual under 100 cc; unchanged or improved upper urinary tracts; no complications for more than 90 days	8 success; 3 failure; 5 unknown (follow-up less than 90 days)	Best results occurred in patients with normal bladders and incompetent sphincters Urethral erosion was major complication
Rosen prosthesis	Rosen (1978)	Case Series (N = 23)	Most post-prostatectomy	Continence	77% success	8 patients had second operation: 3 had device successfully changed; 5 had device removed because of infection (4) or urethral damage (1)
Rosen prosthesis	Rosen (1978)	Case Series (N = 16)	14 post-prostate surgery	Cured = continent most of the time	11	Five failures included: failure of scrotal reserve; urethral and perineal fistula; persistent perineal pain; persistent incontinence
Rosen prosthesis	Augspurger (1981)	Case Series (N = 17) 0-26 month follow-up	Post-prostate surgery	Proper prosthesis function regardless of number of operations	53% success	Half of failures (4) had a possibility of replacement (e.g., mechanical failure); other half caused by perineal pain (2) and multiple complications (2); 15 patients had major complications requiring another operation with replacement or removal of prosthesis
Silicone-gel prosthesis	Kaufman (1978)	Case Series (N = 184) 6-12-month follow-up	168 post prostate surgery	Excellent = patient satisfaction and no pads used Good = patient uses fewer than four pads a day for stress incontinence Failure = no improvement or patient uses more than four pads a day	169 excellent or good 15 failure	11% had major complications (mostly urethral erosions) After 1 year with one or more injection: 33% excellent; 28% good; 39% failure Overall, 69% benefit
Silicone-gel prosthesis	Confer and Beall (1981)	Case Series (N = 8) 30-month follow-up	Post-prostate surgery	Continence without complications regardless of number of injections	100% success	One patient required a second injection 2½ years later
Periurethral Teflon injection	Politano (1978)	Case Series (N = 125; 77 m, 43 fe) Ages 6-84	75 post-prostate surgery; variety of other conditions	Excellent = total continence with no protective device Good = collecting device not necessary Poor = little or no improvement	70% good/excellent	
Periurethral Teflon injection	Lim, Ball, and Feneley (1983)	Case Series (N = 28) Ages 20-84; Mean = 56.9; 3-12 month follow-up	All incontinent; 26 had previous surgery to relieve incontinence	Cured = total continence Temporary improvement = good control of continence with only minimal leakage	21% cured; 54% temporary improvement; 25% no improvement	Patients with weak sphincters and stable bladders responded best

Table 3-1.—Sphincter Devices—Continued

Sphincter device	Reference	Study design	Diagnosis	Criteria for improvement	Results	Comments
Four recent studies[a]	Light	Case Series (N = 58) Ages 12-67, 3-36 month follow-up	All spinal cord	Continence without complications	70%	
	Diokno	Case Series (N = 23) Follow-up mean = 3.5 years		Continence without complications	70%	6 failures from tissue erosion; 1 from infection
	Mulcahy	Case Series (N = 70)		Continence without complications	89%	Complications included 11 cuff erosion; 4 tubing kinks; 3 cuff leaks; 3 pump erosions
	Barnett	Case Series (N = 262)	All had previous surgery for incontinence	Continence without complications	50%	
		(N = 30)	None had previous surgery for incontinence		95%	

[a]Presented at the 1983 Annual Meeting of the American Urological Association and reported in Hager, 1983.

SOURCE: J. Ouslander and R. Kane, University of California at Los Angeles, 1984.

period. Some of the patients required repeated injections, and urethral erosion (similar to complications described with artificial sphincters) occurred in a few patients (38,88).

In addition to the silicone-gel prosthesis, a method of periurethral injection of Teflon has been developed (31). This procedure is quite simple and requires only local anesthesia and the injection of a Teflon paste around the urethra. As with the silicone-gel prosthesis, fewer than 200 cases have been reported; approximately 70 percent achieved favorable results. Experiments with dogs have indicated that the Teflon particles can migrate: They have been found in the dogs' lungs and other major organs (97). Thus, before this technique can be widely instituted, larger sized Teflon particles may have to be developed to prevent migration and any potential long-term adverse effects of these articles in various areas of the body.

ELECTRICAL STIMULATION

Several different approaches involving electrical impulses for the treatment of incontinence have been tested over the last 20 years (149). In the earliest investigations, electrodes were implanted into the pelvic floor musculature and electrical current was used to stimulate muscle contraction and maintain continence in patients with stress incontinence. Difficulties with mechanical failure and migration of the surgically implanted electrodes led to the development of external electrical stimulation. External techniques include anal plugs and pessary-like devices with electrodes.

Electrical stimulation has been used for both acute and chronic conditions. In acute situations, the maximum voltage that does not produce discomfort is used to stimulate for periods of approximately 30 minutes. Stimulation can be repeated on several occasions over the course of a few weeks. In chronic situations, the device is left in place for most of a 24-hour period and the pelvic floor musculature is intermittently stimulated as the current is turned on and off for several seconds at a time.

Scandinavian studies done in cats and humans have shown that these devices can be used for both stress incontinence and incontinence associated with bladder instability (50,51,53,54). In stress incontinence, stimulation appears to work by causing contraction of the pelvic floor musculature through stimulation of the nerves that innervate (i.e., control) the muscles. For bladder instability, the device stimulates sensory nerve fibers, which then cause reflex relaxation of the bladder, mediated by the spinal cord.

These different effects occur at different frequencies of stimulation. Thus, it appears that optimal design of the device involves the ability to vary the stimulation frequency. Because the effects are mediated by nerve fibers, the electrodes must be placed and maintained in the proper position for nerve stimulation to be effective. Recently developed electrical stimulators are inflated in the vagina to minimize electrode movement.

Patient selection is important in the success of these devices. Urologic examination must be performed to determine the type of incontinence and rule out abnormalities treatable by other means. Patients with stress incontinence must have intact pelvic floor musculature to be eligible. Patients with unstable bladders must have an intact nervous reflex arc. Patients with disorders that have completely destroyed the peripheral nerves or lower spinal cord are not appropriate candidates. In addition, patients must be willing and able to use and manage this device on an acute or chronic basis.

Results of several reported case series (shown in table 3-2) vary, depending on the nature of the electrical stimulation. In general, between 50 and 80 percent of individuals derive some short-term benefit from the treatment. A much smaller proportion of patients enjoy long-term benefits. Although there were few serious complications re-

Table 3-2.—Electrical Stimulators

Electrical stimulator device	Reference	Study design	Diagnosis	Criteria for improvement	Results	Comments
Implantable pelvic floor stimulator[a]	Merrill, Conway, and DeWolf (1975)	Case Series (N = 14; 9 m, 5 fe) Ages 3-70	Most had neurologic disorders; 6 postoperative	Dry for at least 3 hours for several days in a row	3 cured; 4 improved	No surgical complications: procedure uniformly unsuccessful for those with lower motor neuron lesions or meningomyelocoele; equipment failures (fractured antenna leads (4); faulty power supply (?)) occurred in 43% of failures
Implanted electrical stimulators[a]	Alexander (1976)	Case Series (N = 22 fe) 3-24 month follow-up	Stress incontinence, usually with coexisting urge incontinence	Cure = continence Improved = subjects relieved but not totally continenct	8 cured after surgery without using implant; 13 improved with surgery and implant stimulation	Relapses associated with influenza, gallbladder surgery, bladder uncomfortable, blow on the abdomen, domestic strife
Transrectal external pelvic floor stimulator	Merrill, Conway, and DeWolf (1975)	Case Series (N = 6 fe)	Stress, congenital iatrogenic postoperative incontinence	Continence	50%	Abdominal cramps and mild diarrhea occurred during stimulation; no equipment failure
Transrectal stimulator	Merrill (1979)	Case Series (N = 20) 5-12 month follow-up	Urinary incontinence and detrusor hyperreflexia	Cure = continence without stimulator Benefit = symptoms less than before implant	0 cured; 4 benefited	Patient instructed to activate device continually except when voiding; ¾ successes after first day
External stimulating device	Doyle, et al. (1974)	Case Series (N = 120)	104 sphincter weakness 12 bladder dysfunction 4 both	Success = continence	37% success 42% success 75% success	Success rate highest in young, nulliparous patients who had not had surgery and was lowest in older patients who had had pregnancies and previous surgery
Maximal perineal stimulation	Glen, et al. (1976)	Case Series (N = 19)	Urinary incontinence; 17 poor urethral pressure profiles	Subjective	0 reported benefit	
Chronic electrical stimulation	Godec, Cass, and Ayala (1976)	Case series (N = 72; 34 m, 38 fe)	38 hyperreflexive bladder; 12 pelvic floor weakness; 16 both	Cured = dry when off device one month Improved = less wet than before stimulation	17 cured; 49 improved; 6 failure 12% success rate overall	Failures caused by urethral stricture (2), urinary tract infection (2), radiation cystitis (1), mental retardation (1)
Acute electrical stimulation	Godec and Cass (1978)	Nonrandomized study of different types (N = 29; 8 m, 21 fe) 4-17 month follow-up	8 stress incontinence; most others had neurologic disorders	Relief = dry Improved = less wet	Overall 17/20 relief or improvement; 5/17 relapsed, requiring repeat treatment	

Table 3-2.—Electrical Stimulators—Continued

Electrical stimulator device	Reference	Study design	Diagnosis	Criteria for improvement	Results	Comments
Maximal electrical stimulation (MES)	Plevnik and Janez (1979)	Case Series (N = 98)	37 mixed stress and urge incontinence; 11 postprostate surgery; remainder had various types of neurogenic bladder	Success = continence	Overall: 7% cured; 50% improved; 43% no effect	In some patients, 3 MES sessions resulted in sustained improvements
Electronic pessary	Harrison and Paterson (1970)	Case Series (N = 21 fe) Ages 37-70	15 stress incontinence; 5 urge incontinence; 1 dribbling incontinence (duration of symptoms = 9 mo. to 38 yrs)	Symptoms cured or improved	11 success	
Electric pessary	Hill, et al. (1968)	Case Series (N = 5 fe) 12 week follow-up	2 stress incontinence; 1 urge incontinence; 1 postsurgical incontinence	Continence	4 improved	
Intravaginal electrical stimulation (IVS)	Erlandson, Fall, and Sundin (1977)	Case Series (N = 50 fe) Ages 19-82	24 stress incontinence; 22 urgency with or without incontinence	Urethral pressure profile used to determine effect of electrical stimulation on urethral closure	20-50 Hz for 15 mins. was most effective for urethral closure	Carefully selected positions of electrodes and proper frequency of electrical impulse were necessary for optimal urethral response
IVS	Fall, et al. (1977)	Case Series (N = 17 fe) Ages 27-60, mean = 46	Idiopathic urinary urgency without incontinence	Bladder capacity increase before urination	Bladder capacity less than 300 ml.: 7/9 increased; 2/9 decreased Bladder capacity more than 300 ml.: 3/8 increased; 5/8 decreased	
Long-term IVS (4-9 months)	Fall, et al. (1977)	Case Series (N = 24 fe) Ages 30-60, mean = 46; 2-8 month follow-up	9 urge incontinence; 9 stress incontinence; 6 both	Cured; free from symptoms or marked improvement; no improvement	Urge incontinence 1/9 cured; 8/9 improved Stress incontinence 3/9 cured; 4/9 improved; 2/9 not improved Both types 1/6 cured; 5/6 improved	

[a]Not defined

SOURCE: J. Ouslander and R. Kane, University of California at Los Angeles, 1984

ported with these devices, the long-term effects of chronic electrical stimulation are unknown. Several reports indicated that patients simply refused to use the device for a long period of time.

Several features of the case series reviewed in table 3-2 should be emphasized. Many of these series were done before information on optimal frequencies and durations of stimulation for the different types of incontinence were known. Thus, the success rate using optimal parameters of stimulation is unknown. Unlike the situation for artificial sphincters, which requires a sham operation to design a true controlled trial, a controlled trial of intravaginal electrical stimulation to test possible placebo effects is much more feasible. Despite the possibility, no controlled studies have been reported. Comparing the effects of the functioning intravaginal electrical stimulator with the effects achieved by simply placing the device without the electrical stimulation would be of great interest in light of reports in which patients had prolonged cures after single treatments or claimed success when batteries were malfunctioning.

CATHETERS

There are three basic types of catheter techniques used to manage incontinence: chronic indwelling catheterization, intermittent bladder catheterization, and external catheters (for men). Chronic in-dwelling catheterization involves the placement of a catheter in the bladder, held in place by an inflated balloon. The catheter is attached to plastic tubing, draining urine into a drainage bag, which is emptied at regular intervals. The drainage bag can be strapped to the leg and hidden beneath clothing to avoid embarrassment. Despite improved techniques of chronic indwelling catheterization, this type of treatment is associated with several potentially severe complications and is probably overused in the management of incontinence (especially for elderly patients in long-term care institutions) (98,110, 120,166).

Continuous in-dwelling catheterization is appropriate for managing established incontinence in only a limited number of patients. They include individuals with urinary retention (caused by either anatomic or functional obstruction or poor bladder emptying) that cannot be relieved surgically, pharmacologically, or by intermittent catheterization, and patients with skin conditions that are worsened by contact with urine. Surveys of long-term care institutions in this country and Canada indicate that 10 to 30 percent of incontinent individuals are managed by continuous indwelling catheterization (85,98,111,120). This number probably far exceeds the number of patients with the above-mentioned conditions, but catheters are probably used for staff convenience and because of cost considerations (if one ignores the costs of treating complications that result from catheterization). The cost implications are discussed later in this study.

The primary risk of chronic in-dwelling catheterization is urinary tract infection. Virtually all patients with in-dwelling catheters for periods over 2 weeks will have urinary tract infections; however, not all these patients will become symptomatic and require treatment (166). Urinary catheterization has been shown to be the major cause of nosocomial infections in acute care hospitals (77,144) and are associated with increased mortality in this setting (116).

Studies over the last two decades have shown that maintaining a closed drainage system and adeptly handling the catheter and draining its bag are critically important in preventing infection (68,177). Other techniques, such as one-way valves in the catheter tubing to prevent backflow of urine and separate ports added to the catheter for urine sampling, have also decreased the risk of infection. Prophylactic antibiotic therapy, either directly instilled into the bladder or taken orally, does not prevent urinary infections and, in fact, appears to predispose to infection with more resistant bacteria (70,91,106,165). Frequent cleaning of the area of catheter entry with antimicrobial substances increases rather than decreases the incidence of infection (26). Thus it

appears that techniques involving frequent manipulation of the catheter or breaking of the draining system increase the risk of infection and should be avoided. A few recent reports indicate that antimicrobial substances, such as peroxide and iodine solutions, instilled regularly into the drainage bag, diminish the incidence of infection (39, 96,143). The ability of these techniques to prevent symptomatic infections to patients continuously catheterized for years is still unproven.

An alternative approach to continuous indwelling catheterization is intermittent self-catheterization. This technique has been applied mainly in younger individuals with paraplegia or other neurologic disorders (e.g., spina bifida) whose bladders do not contract or empty properly (92). It is also applicable for patients with other causes of chronic urinary retention such as a diabetic neuropathic bladder. These patients are taught to catheterize themselves at regular intervals. The procedure involves no special equipment except a catheter, which is kept in an antiseptic solution between catheterizations. This technique has been shown to reduce the incidence of infection and other complications compared with continuous in-dwelling catheterization in younger patients (92). Intermittent catheterization is less often used in the elderly incontinent patient; however, it would be applicable in those whose incontinence is associated with urinary retention not correctable by other means. Either the patient or the caregiver must be trained in the technique. Because complications with this technique might be more frequent in this patient population than in others, studies comparing the efficacy of chronic in-dwelling versus intermittent catheterization in the elderly population would be of value.

External catheters (condom catheters) are used exclusively in men. Although this technique is thought to diminish the risk of urinary tract infection, no studies have confirmed this impression. External catheters require changing every 24 to 48 hours, and they frequently fall off, requiring reapplication. Certain types of catheters and application techniques reduce the frequency with which the catheter falls off. A substantial proportion of patients develop skin irritation on the penis (balanitis), which precludes the use of these catheters; the patient then requires an in-dwelling catheter until the skin lesions heal. External catheters, like intermittent catheterization, require either the patient or, more commonly, a caregiver to be available and trained in the proper management techniques.

BEDPADS AND UNDERGARMENTS

Most acute care hospitals and long-term care institutions use "blue pads" for managing incontinence, despite their relatively poor absorbency and lack of odor control. A variety of other products are available for keeping patients' bedding, clothing, and furniture dry in these settings. Specially designed incontinence undergarments and bedpads have been used for several years in Great Britain, other European countries, and Australia, but only over the last 2 to 3 years have several of these products been marketed intensely in the United States.

Ideally, an incontinence bedpad or undergarment should be highly absorbent, nonallergenic, and relatively easy for patients or caregivers to change. It should control odor, not wrinkle (which predisposes to skin irritation and impairs healing of pressure sores), and require fewer changings than simply using drawsheets or other types of padding (152,171). The most innovative bedpad is the Kylie pad, which was developed in Australia. This pad is launderable, has a porous top layer that allows urine to pass freely into a more absorbent middle layer, and a moisture-resistant backing that keeps the bed dry. Unlike other types of bedpads, the Kylie pad's special design helps keep both the patient and the bed or furniture dry (24,175).

Incontinence undergarments come in many shapes and forms. Some are completely disposable; others are launderable briefs into which a disposable pad is inserted. An increasing number of these products is being marketed in this country. Most are designed along the lines of the Kylie

bedpad, with a permeable layer close to the patient, a highly absorbent middle layer or pad (which generally contains a polymer with tremendous absorptive capacity), and an outer layer, which prevents soiling of clothing.

Several small-scale studies have examined the impact of these products on patient comfort and health (table 3-3). Most of the studies are uncontrolled and do not account for patient cross-overs between treated and untreated groups.

As might be expected, most patients responded favorably. A few studies suggested that costs decreased because the reduced amounts of clothing and bedding required decreased the laundry and labor needs, thus lowering costs. These types of products can clearly make life more comfortable for incontinent persons and diminish the burden on their caregivers by keeping the affected individuals dry and more mobile and by enhancing their ability to interact socially. However, carefully designed, controlled studies with objective outcomes that compare these products with other strategies to manage incontinence would be of great value, especially in the incontinent population now in long-term care institutions. No studies have carefully assessed the effectiveness of these products in diminishing such complications of incontinence as skin irritation and urinary tract infection. Studies that examine the effectiveness of these products in diminishing the burden on caregivers of community-dwelling elderly and in delaying or preventing institutionalization would also be of great interest.

SURGERY

Surgical treatment is essential in the management of certain types of incontinence and effective, but not essential, for other types. For those patients with overflow incontinence caused by an anatomic obstruction to urine flow (e.g., an enlarged prostate in men or a urethral stricture), surgery is necessary to relieve the obstruction. Although this type of surgery may not always cure the incontinence (in fact, in some instances, the incontinence may persist or even worsen), urinary obstruction cannot be left untreated. Continuous retention of urine will predispose the patient to recurrent urinary tract infections and could eventually lead to renal failure and death. In some patients, pathologic conditions in the lower genitourinary tract, which irritate the bladder or urethra and cause incontinence, can be corrected surgically. Examples of such conditions include bladder tumors, bladder stones, and diverticuli of the bladder or urethra, as well as several other, less common conditions.

The most common surgical procedure for incontinence is bladder-neck suspension. In this operation in women with stress incontinence, the bladder neck and urethra are repositioned. Several modifications of the original bladder-neck suspension procedure have been developed, and the procedure can now be done in less than an hour, under local or spinal anesthesia (124). Hospital stays can be as short as 3 days. Because women with symptoms of stress incontinence can also have other abnormalities of genitourinary tract function (e.g., bladder instability and urinary retention), careful preoperative evaluation and appropriate patient selection are critical to success. Most published series have shown a 70 to 90 percent success rate (99,123,124,146). No prospective, randomized, controlled study has been done to compare bladder-neck suspension to other treatments for stress incontinence—e.g., electrical stimulation or drug treatment—in similar groups of patients.

DRUG TREATMENT

Drugs can be used to treat overflow, stress, and urge incontinence (14,109,122). For those patients with overflow incontinence caused by poor bladder contraction (rather than anatomical obstruction to urine flow), cholinergic drugs that promote bladder contraction can be used. The most com-

Table 3-3.—Bedpads and Undergarments

Device	Reference	Study design	Diagnosis	Criteria for improvement	Results	Comments
Launderable bed pad (Kylie)	Broughten (1979)	Nonrandomized crossover study of drawsheet and disposable pads vs. Kylie pad (N = 18), age = 65+	85% incontinent of urine; 50% incontinent of urine and stool	Nurses' reactions; patient's reactions; skin condition and costs	Kylie pads decreased odor, made patients more comfortable; improved skin conditions; reduced laundry by 45%	Estimated cost savings per patient per night = $24.20
Launderable bed pad (Kylie)	Smith (1979)	Uncontrolled (N = 8) age = 65+	All incontinent of urine at night and prone to pressure sores	Nurses' assessments of Kylie pad's ability to: absorb large volume of urine; retain moisture under pressure; keep patient's skin dry; keep bed dry reduce risk of bed sores; avoid wrinkling; give patient comfort; reduce odor; be economical	Kylie pads allowed patients to sleep better; saved time; saved linen; decreased cost by $1.25 per patient per night	Study performed in two acute-care hospitals
Launderable bed pad (Kylie)	Williams, et al. (1981)	Comparison of disposable bed pads and Kylie with crossover design (N = 36; 11 m, 25 fe) Ages = male 52-87, mean = 73; female 34-101, mean = 77	Most had neurologic disorder causing incontinence	Skin dryness; lack of creasing; less need to change bed linen; less odor; cost savings	Kylie pads reduced skin wetness, creased less often; decreased bed changes; improved odor; reduced cost 39% ($1.25 per patient per day)	
Launderable undergarments with disposable pads (Kanga, Molnlyche, and Sandra pants)	Shepherd and Blannin (1980)	Each subject wore each garment for a month (N = 20, 2 m, 18 fe) Ages 4-84	Neurologic disorders	Subject's opinion of garment	Kanga was most satisfactory; Molnlyche was difficult to handle; Sandra was associated with skin irritation, sweating, and discomfort	Most subjects were living in homes and attended by a community nurse
Launderable bedsheet (Kylie pad)	Silberberg (1977)	Randomized comparison of absorbent pad, pad and antimicrobial agent, and drawsheet (N = 32)	Urinary and stool incontinence	Lack of skin moisture; skin inflammation; creasing or wrinkling of pad; odor	Groups with pads had less skin irritation (77% vs. 37%); dryer skin (750/976 vs. 387/1046); less wrinkling (14% vs. 41%), less odor (5% vs. 27%)	Subjects living in long-term care ward
Disposable udergarments (Attends)	Beber (1980)	Randomized comparison of Attends and disposable bedpads; no crossover (N = 276) Age = 65+	Persistent incontinence (3 or more uncontrolled urinations per day)	Nursing staff rate skin conditions and quality of life	40/53 staff judged patient's quality of life as improved (based on social activities and expressed confidence with Attends)	All were nursing-home patients; reduced patient changes; gave some patients greater mobility and less embarrassment; improved odor, appearance, and mood of ward
Launderable brief with disposable pad (Molnlyche pant)	Watson (1980)	Uncontrolled (N = 54; 15 m, 39 fe) Age 60-99	22 "heavy" incontinence, 17 "moderate"; 8 "slight"; 21 also had stool incontinence	Patient comfort, acceptance, and effect on skin	Reduced staff workload, laundry, odor; increased patient dignity, response to toilet training	Subjects in chronic hospital; estimated 90% cost savings for all wards; increase in visitors

SOURCE: J. Oustander and R. Kane, University of California at Los Angeles, 1984.

monly used drug, bethanechol (Urecholine), stimulates bladder contraction and emptying, prevents recurrent urinary tract infections caused by urinary retention, and, in theory, helps resolve the overflow incontinence. In many patients, especially in the elderly age group, this type of treatment may worsen incontinence by creating urinary frequency and urgency. In addition, bethanechol has several adverse side effects, including gastrointestinal cramping, diarrhea, and increased bronchial secretions. Thus, intermittent catheterization may be a better alternative for many of these patients.

Drugs that promote contraction of the smooth muscle around the bladder outlet have been used to treat stress incontinence. These drugs include pseudoephedrine and phenylopropanolamine, both found in over-the-counter cold preparations. No carefully designed studies have been done to compare the effectiveness and risks of drug versus surgical therapy for stress incontinence. Drugs for stress incontinence must be used carefully, especially in elderly women in whom they can exacerbate hypertension and cardiovascular disease. Topical or oral estrogens are frequently chosen to treat stress incontinence in elderly women. Although estrogens strengthen the tissues around the bladder outlet, few studies have objectively documented that this physiologic effect results from estrogen therapy alone, and estrogens do carry the risk of exacerbating hypertension and thromboembolic disease, as well as an increased risk of endometrial cancer (86,169). They are probably useful in women with stress incontinence in whom there are no major contraindications to their use and should be used cyclically in the lowest doses possible. Some experts recommend that they be used in a topical vaginal cream in combination with a progestational agent taken orally to diminish the risk of complications, although topical intravaginal estrogens are absorbed to pharmacologic blood levels, and the relative safety of this mode of administration remains unclear (86).

The most common and effective drug treatment is that for urge incontinence (122,174). Various drugs have been tested for their ability to diminish bladder contractility and thereby improve symptoms associated with bladder instability (table 3-4). Most studies have shown these drugs to be effective in over 50 percent of the patients.

Several caveats are important. The majority of studies have been either uncontrolled or placebo controlled without adequate concern for patient cross-overs between treatments. The patients, their genitourinary abnormalities, their presenting symptoms, and the specific outcomes of treatments have generally been poorly defined. Interestingly, several of the studies mentioned that symptomatic improvement does not always correlate with objective changes in lower genitourinary function (as measured by urodynamic techniques). Most studies did not control for other simultaneous interventions that can also affect outcomes, such as instructions to delay the urge to void, to schedule toileting, and to restrict fluid intake. Finally, most of the drugs used to treat bladder instability have bothersome side effects, including dry mouth, constipation, and blurred vision (122,174).

Several newer classes of drugs, such as prostaglandin inhibitors and calcium antagonists, have also been studied in small numbers of patients. Carefully controlled studies of newer drugs, studies comparing drug treatment to other forms of treatment for detrusor instability, and the development of new pharmacologic agents for this condition would be of great value.

TRAINING PROCEDURES

Several techniques, broadly labeled here as "training procedures," have been reported as successful in managing various types of incontinence (71,74). These techniques include pelvic floor exercises, biofeedback bladder retraining, habit training, and behavioral modification.

Repetitive contraction of muscles of the pelvis and vaginal wall (Kegel exercises) have been used for several decades in the management of stress incontinence in females (89). Although these exercises are often not curative and can only be used by patients with adequate cognitive function, in-

Table 3-4.—Drugs in Incontinence Treatment

Drug	Reference	Study design	Diagnosis	Criteria for improvement	Results	Comments
Diminish bladder contractions:						
Propantheline 30 mg orally qid or more	Tulloch (1978)	Uncontrolled (N = 33); ages = 14-79, mean = 62	Unstable detrusor	Symptoms	2 symptomatic improvements	14/20 needed long-term therapy to maintain improvement
Propantheline 60 mg IV Imipramine 25-75 mg IM	Diokno, et al. (1972)	Uncontrolled (N = 11)	Uninhibited bladder contractions	Urodynamic	Propantheline abolished uninhibited bladder contractions; Imipramine did not	
Propantheline 15 mg orally weeks Oxybutinin 5 mg orally 4-6 weeks	Thompson and Lauvetz (1976)	Double-blind, placebo controlled (N = 14)	Uninhibited neurogenic bladder	Urodynamic	Both delayed reflex contractions, increased bladder volume at first contraction, and subjectively decreased urge incontinence	Oxybutinin was better than propantheline; had fewer side effects over 4-6 week period
Propantheline 30 mg po Flavoxate 200 mg po	Kohler and Morales (1968)	Double-blind, no placebo (N = 23 m, 2 fe)	21 bladder spasticity 4 flaccid-bladder	Urodynamic	Both raised bladder capacity 2 hours after dose; 13/21 flavoxate; 8/21 propantheline	No change in intra-ocular pressure
Propantheline 30 mg orally qid 7 days Flavoxate 200 mg orally qid 7 days	Badley and Cazort (1970)	Double-blind, no placebo (N = 46; 18 m, 28 fe)	Urinary symptoms	Symptoms	Both improved symptoms	11 urinary infection; 25 cystitis; no change in ocular pressure
Propantheline 15 mg orally qid 3 weeks Dicyclomine 10 mg orally 3 weeks	Beck, Aruusch, and King (1976)	Uncontrolled (N = 82)	Detrusor overactivity, stress incontinence	Symptoms Urodynamic	76% of 64 propantheline; 67% of 18 dicyclomine improved or cured	
Propantheline 15 mg orally qid 3 weeks Dicyclomine 10 mg orally qid 3 weeks	Beck, Aruusch, and King (1976)	Placebo, controlled (N = 51)	Detrusor overactivity, stress inactivity	Symptoms	75% of 15 propantheline; 62% of 13 dicyclomine; 15% of 15 placebo improved	
Propantheline 15 mg orally Atropine 0.6 mg IM Ephedrine 15 mg orally Orphenodrine 50-100 mg orally Others	Brocklehurst and Dillane (1967)	Uncontrolled, All subjects elderly	Incontinence	Incontinence charts, urodynamics	Combination of propantheline and orphenadrine gave best clinical and urodynamic improvement	Total of 13 drug combinations Clinical improvement did not correlate with urodynamic changes
Propantheline 15 mg orally combined with Imipramine 25 mg qid orally	Fliegner and Glenning (1979)	Uncontrolled (N = 258)	Urge and stress incontinence	Symptoms	90% with urge incontinence improved	Not all subjects received both drugs; some received other agents
Propantheline 15 mg adults IM; 7.5 mg children IM	Blaivas, et al. (1980)	Uncontrolled (N = 42; 9 m, 33 fe) ages = 5-79, mean = 62	Uninhibited detrusor contractions	Urodynamic	79% positive response to propantheline; 50% urinary retention	No patient who failed to respond to parenteral medication had favorable response to drug when administered orally
Emepronium bromide 50 mg orally qid 2-4 weeks	Brocklehurst, Armetage, and Jouhar (1972)	Placebo controlled; crossover unblinded (N = 43) ages = 57-90; mean = 82	Incontinence	Nursing records	Small reduction in incontinence with active drug	
Emepronium bromide 200 mg orally qid for one month	Nordling, et al. (1979)	Uncontrolled (N = 38) ages = 18-90, mean = 51	30 uninhibited contractions	Symptoms	66% improved	
Emepronium bromide 50 mg IM dose 200 mg orally qid 7-10 days	Ritch, et al. (1977)	Uncontrolled (N = 9; 6 m, 3 fe) ages = 71-94, mean = 82	Established incontinence, uninhibited contractions	Urodynamic	Only IM decreased contractions and a raised bladder capacity and had little effect on urodynamics	

Table 3-4.—Drugs in Incontinence Treatment—Continued

Drug	Reference	Study design	Diagnosis	Criteria for improvement	Results	Comments
Emepronium bromide 200 mg qid orally Flavoxate hydrochloride 200 mg orally qid	Stanton (1973)	Double-blind randomized crossover, no placebo (N = 38, 6 m, 32 fe) mean age = 47	Urinary symptoms and incontinence	Symptoms Urodynamic	Flavoxate better for relief of symptoms; no change in urethral pressure profiles	38% showed no clinical effect from either drug
Emepronium bromide 200 mg orally qid 21 days	Williams, Prematalake, and Palmer (1981)	Double-blind placebo controlled (N = 30, 8 m, 22 fe) mean age = 74	Organic brain disease, functional psychiatric disorder, incontinence	Symptoms	No significant difference between placebo and emepronium	
Emepronium bromide 200 mg tid Propantheline 3 × 30 mg for 12 weeks	Gaudenz and Weil (1980)	Placebo controlled (N = 70)	Motor urge incontinence	Symptoms Urodynamic	Emepronium bromide, 34% excellent; flavoxate, 50% excellent; propantheline, 15% excellent; placebo, 0%	Uninhibited detrusor contractions persisted
Emepronium bromide 200 mg tid OR placebo in two 4-week periods	Walter, et al. (1982)	Double-blind crossover (N = 20; 8 m, 12 fe) ages = 64-88; mean = 74	Urinary incontinence and frequency	Symptoms Urodynamic	No statistically significant difference between effects of emepronium bromide and placebo; overall subjective cure rate = 79%	
Emepronium bromide 200 mg qid OR Flavoxate chloride 200 mg qid OR Placebo	Meyhoff, Gerstenberg, and Nordling (1983)	Double-blind crossover (N = 20) ages = 22-79; median = 51	Motor urge incontinence without bladder suspension defect	Subjective	79% claimed good effects from one or more drugs; 47% preferred placebo Only placebo had statistically significant decrease in frequency of voidings, incontinence, and nocturia No differences demonstrated between emepronium bromide and flavoxate chloride	
Flavoxate 100 mg IV 200 mg orally qid 7 days	Briggs, Castleden, and Asher (1980)	Uncontrolled (N = 6, 2 m, 4 fe) ages = 72-84	Uninhibited contractions	Symptoms Urodynamic	No consistent effect on symptoms or urodynamic parameters	
Flavoxate 200 mg IV Emepronium bromide 50 mg IM Imipramine 50 mg IM	Cardozo and Stanton (1979)	Uncontrolled (N = 15)	Detrusor instability	Urodynamic	Emepronium significantly improved urodynamic parameters; flavoxate and imipramine had no significant effect	
Flavoxate 50 mg orally qid 14 days Methanteline 50 mg orally qid 14 days Meladrazine 150 mg orally qid 14 days	Hebjorn (1977)	Double-blind crossover, no placebo (N = 34; 8 m, 26 fe) ages = 23-65; mean = 47	Multiple sclerosis; incontinence; detrusor hyperreflexia	Symptoms as recorded in a patient diary Urodynamic	27/32 had improved symptoms; 18/27 preferred methanteline	9 chronic urinary infection; patient satisfaction did not correlate well with urodynamic changes
Flavoxate 200 mg qid	Younglove, Newman, and Wall (1980)	Uncontrolled (N = 25)	Unstable bladder	Symptoms	21 cured	
Methanteline 50 mg orally qid 6 months	Walter (1978)	Uncontrolled (N = 54) ages = 29-82; mean = 54	Uninhibited contractions	Symptoms Urodynamic	27/53 improved or free of symptoms	Only half those improved had increased bladder by cystometry; no other urodynamic changes
Dicyclomine 20 mg IM 20 mg orally tid 8 weeks	Awad, et al. (1977)	Uncontrolled (N = 27; 14 m, 13 fe) ages = 10-90	Uninhibited neurogenic blaoder	Symptoms Urodynamic	Most had increased bladder capacity with oral or IM; 26 increased bladder capacity an average of 21 sec; 24 had symptomatic improvement	No significant side effects, improvement started at 7-10 days and continued after 4 weeks; females had more symptomatic improvement
Dicyclomine 20 mg orally	Fischer, et al. (1978)	Uncontrolled (N = 14; 6 m, 8 fe)	Uninhibited neurogenic bladder	Urodynamic	17% excellent; 7% good; 22% fair	No complications

Table 3-4.—Drugs in Incontinence Treatment—Continued

Drug	Reference	Study design	Diagnosis	Criteria for improvement	Results	Comments
Imipramine 50-100 mg orally in divided doses 1-2 weeks	Cole and Fried (1971)	Uncontrolled (N = 9)	Spinal cord injury or disease and neurogenic bladder	Symptoms Urodynamic	6 improved continence	3 with urodynamic follow up had increased bladder capacity
Imipramine 50-150 mg for up to 2 weeks	Castelden, et al. (1981)	Uncontrolled (N = 10, 2 m, 3 fe) ages = 63-88, mean = 88	Detrusor instability	Symptoms Urodynamic	6 became continent, urodynamics improved	2 had symptomatic postural hypotension; no correlation with plasma drug levels
Oxybutinin	Moisey, Stephenson, and Brenoler (1980)	Double-blind placebo controlled crossover (N = 26, 10 m, 13 fe) ages = 20-79	Detrusor instability	Symptoms Urodynamic	69% had symptomatic improvement; 40% had urodynamic improvement	8% placebo response, symptomatic improvement not correlated with urodynamic changes, dry mouth common side effect
Oxybutinin	Younglove, Newman, and Wall (1980)	Uncontrolled (N = 3)	Unstable bladder	Symptoms	100% improved	
Oxybutinin (a) 5 mg oral dose (b) 5 mg orally bid or tid 7-14 weeks	Diokno and Lapides (1972)	Uncontrolled (N = 8)	Uninhibited bladder contractions	Symptoms Urodynamic	7 had decreased frequency or amplitude of uninhibited contractions Improved symptoms	3 given 15 mg propantheline orally in separate trial; this also decreased contractions
Strengthen bladder outlet: Norephedrine 100 mg orally bid	Ek, et al. (1978)	Double-blind placebo controlled crossover (N = 25) mean age = 54	Stress incontinence	Symptoms Urodynamic	12/22 improved, 2 became continent; urethral pressure increased in erect and supine positions	Urodynamic changes correlated with symptomatic improvement
Norephedrine 100 mg orally bid 3 weeks	Obrink and Bunne (1978)	Uncontrolled (N = 10) ages = 33-67; mean = 52	Stress incontinence	Symptoms Urodynamic	1 improved, no change in bladder or urethral pressure	7 got headaches, all subjects on estrogens
Norephedrine 75-100 mg orally 1 dose	Ek, Andersson, and Ulmsten (1978)	Uncontrolled (N = 6) ages = 39-66; mean = 55	Stress incontence	Urodynamic	Urethral pressure increased in all subjects	2 got headaches; mean blood pressure increased from 130/83 to 178/96
Ephedrine 25 mg orally bid 1-18 mos	Rashbaum and Mandlebaum (1948)	Uncontrolled (N = 82) ages = 41-70	Incontinence	Symptoms	41% of 68 improved; 40% of 68 cured	52 had previous pelvic surgery
Ephedrine 44-200 mg orally in divided doses for 1-17 mos	Diokno and Taub (1975)	Uncontrolled (N = 38, 20 m, 18 fe) ages = 7-77	Incontinence	Symptoms	27 good to excellent response	
Ephedrine 15-30 orally 3 × daily 2-6 weeks	Castleden, et al. (1982)	Uncontrolled (N = 24, 8 m, 16 fe) ages = 68-90; mean = 79.5	Unstable detrusor contractions	Symptoms Urodynamic	32% continent; 55% improved; 13% same	Urodynamic improvement did not reach statistical significance; training techniques also used
Phenypropanalamine 50 mg orally (1 spansule Ornade)	Montague and Stewart (1979)	Uncontrolled (N = 12)	Stress incontinence	Urodynamic	11 had at least 20% increase in urethral pressure	
Chlorpheniramine maleaxe and phenylpronolamine (twice daily	Younglove, Newman, and Wall (1980)	Uncontrolled (N = 14)	Unstable bladder	Symptoms	12 cured	
Phenylpropanalamine 50 mg orally bid (1 spansule Ornade) for 3 mos to 3 yrs	Stewart, Banowsky, and Montague (1976)	Uncontrolled (N = 88; 11 m, 77 fe)	Females—stress incontinence (documented in 32), males—prostatectomy incontinence	Symptoms	59% females and 27% males had significant improvement	
Phenylpropanalamine 50 mg orally bid for up to 4 weeks	Awad, et al. (1978)	Uncontrolled (N = 20; 7 m, 13 fe)	Females—stress incontinence; males—post-prostatectomy incontinence	Symptoms Urodynamic	11 females improved or became continent, 6 men improved, all with urodynamic follow up had increased urethral pressure	

Table 3-4.—Drugs in Incontinence Treatment—Continued

Drug	Reference	Study design	Diagnosis	Criteria for improvement	Results	Comments
Estrogen therapy:						
Estradiol 2 mg + estriol 1 mg daily	Walter, et al. (1978)	Double-blind controlled; no crossover (N = 29) ages = 55-69; mean = 56	All postmenopausal stress incontinence but no detrusor hyperreflexia	Symptoms Urodynamic	8 cured (of these 1 had placebo); no significant urodynamic changes	No one experienced side effects; significant difference betwen placebo and estrogen; demonstrated influence of estrogen on urethral and vaginal mucosa
Estriol 2 mg day for 2-4 months	Faber and Heidenreich (1977)	Controlled (N = 41)	All postmenopausal with stress incontinence grades II and III (clinical categories after Ingelman-Sundberg)	Urodynamic Symptoms	95% had significant urodynamic improvement; 34% subjective improvement	No patient maintained complete continence
Estradiol benzoate 4,000-10,000 RU 2-3 wk Estradiol Depropionate 1-2 mg 3/wk IM	Salmon, Walter, and Geist (1941)	Uncontrolled (N = 16) ages = 57-72	10 stress incontinence; 6 urinary frequency	Symptoms	12 had relief over 4-month follow-up	Symptoms returned 6 weeks to 9 months after treatment; recurrent symptoms responded to estrogen therapy
Estradiol 2 mg/day for 3 wks then 1 mg/day	Ek, et al. (1980)	Uncontrolled (N = 16) ages = 38-71; mean = 61	All postmenopausal stress incontinence	Urodynamic Symptoms	No statistical urodynamic change; 1/13 improved; 10/13 no change; 2/13 got worse	
Estradiol 2 mg/day for 3 wks OR Estriol 8 mg/day for 3 wks	Rud (1980)	Uncontrolled (N = 30) ages = 37-78; mean = 61	27 postmenopausal 24 stress incontinence	Subjective Urodynamic	17/24 improved; no significant change in urodynamic parameters	
Estriol injection 80 mg every 4 wks with phenylpropanolamine 50 mg twice daily	Beisland, Fossberg, and Sander (1981)	Uncontrolled (N = 14) ages = 54-94; mean = 77	Urinary incontinence from incomplete urethral closure mechanism	Symptoms Good = continent Improved = continent occasionally Unchanged	8 good; 4 improved	No serious side effects
Other drugs:						
Baclofen 5 mg orally per day for 28 days	Taylor and Bates (1979)	Double-blind, placebo-controlled crossover (N = 40; 13 m, 27 fe)	Unstable bladder	Symptoms	Improved symptoms	Some improvement also noted with placebo
Nitedipine 10-20 mg orally bid for 1 week	Rud, Andersson, and Ulmsten (1979)	Uncontrolled (N = 10) ages = 9-63; mean = 33	Urge incontinence	Symptoms Urodynamic	All had symptomatic improvement; uninhibited contractions abolished	
Methyldopa 250-2,000 mg day in divided doses for up to six months	Raz, et al. (1977)	Uncontrolled (N = 50)	Neurogenic bladder with residual urine; 38 upper motor neuron (mostly multiple sclerosis); 12 lower motor neuron	Symptoms Urodynamic	19/38 improved; 5/12 improved; urodynamics unchanged after one week	
Bromocriptine up to 2.5 mg orally bid Indomethacin up to 100 mg orally bid	Cardozo and Stanton (1980)	Single-blind crossover (N = 40) mean age = 53	Detrusor instability	Symptoms	More symptomatic improvement with indomethacin	Prominent side effects with both drugs
Bromocriptine 5 mg/day	Farrar and Osborne (1976)	Uncontrolled (N = 24; 7 m, 17 fe) ages = 17-22	Detrusor instability	Symptoms	14 benefited	Of 10 studied, 5 had marked side effects
Bromocriptine 5 mg/day	Farrar and Osborne (1976)	Double-blind (N = 10)	Detrusor instability	Symptoms	Too small for statistical analysis but those on placebos subsequently improved on Bromocriptine	

Table 3-4.—Drugs in Incontinence Treatment—Continued

Drug	Reference	Study design	Diagnosis	Criteria for improvement	Results	Comments
Bromocriptine 7.5 mg/day OR placebo in a six-week period	Abrams and Dunn (1979)	Double-blind (N = 51, 6 m, 45 fe) ages = 20-68)	Bladder instability	Symptoms Urodynamic	No significant improvement in either symptoms or urodynamic findings seen in bromocriptine compared to control group	
Flurbiprofen 50 mg orally bid for 2 wks	Cardozo, et al. (1980)	Double-blind placebo, controlled crossover (N = 30) ages = 21-74, mean = 49	Detrusor instability; 27 idiopathic; 3 multiple sclerosis	Symptoms Urodynamic	Significant symptomatic improvement; increased bladder volume at first contraction; 6 cured symptomatically and urodynamically	43% side effects (mostly minor)
Flunarazine 20 mg	Palmer, et al. (1981)	Double-blind placebo controlled crossover (N = 14) ages = 35-81	Detrusor instability	Symptoms Urodynamics	11 symptomatic cure with active drug, no significant urodynamic change	No correlation between symptomatic and urodynamic change

KEY: IM = By intramuscular injection
qid = Four times a day
PO = by mouth, orally
tid = three times a day
OR = operating room

SOURCE: J. Ouslander and R. Kane, University of California at Los Angeles, 1984

tact pelvic-floor musculature, and motivation to perform them, they can be useful adjuncts to other forms of therapy, such as surgery, drugs, or electrical stimulation.

Biofeedback has been used in the treatment of both urge and stress urinary incontinence, as well as in fecal incontinence (49,168,172). This procedure involves placing pressure transducers in the bladder or rectum and having the patients try to either inhibit bladder contraction or contract pelvic-floor musculature, depending on the nature of the condition being treated. The pressure transducers can supply both visual and auditory feedback on these physiologic processes. The treatments are performed repeatedly over several weeks and require specialized equipment and personnel and well-motivated patients with adequate cognitive function.

Bladder retraining refers to techniques that help restore normal voiding pattern and continence. These techniques are generally useful after bladder function has been acutely altered. For patients who have had over-distention injuries from acute urinary retention, techniques to stimulate voiding (e.g., running tap water and stroking the lower abdomen and inner thigh) and to help complete bladder emptying (e.g., bending forward and pressing on the lower abdomen) are used, often in combination with intermittent catheterization, until the patient can void properly on his or her own. For those patients who have urge incontinence from a shrunken, inflamed bladder (such as might occur after removal of an indwelling catheter), bladder retraining involves having the patient attempt to delay voiding as long as possible and gradually extend the intervals between voiding. This technique (sometimes referred to in the literature as "bladder drill") has also been used to treat urge incontinence. For bladder retraining to be successful, the patient must have adequate cognitive and physical function, and both the patient and staff must be sufficiently motivated.

Habit training is most useful for patients with functional incontinence, although the techniques may also be useful for those with urge and stress incontinence. In contrast to bladder retraining, the primary objective of habit training is to avoid incontinent episodes, rather than to restore a completely normal pattern of voiding. The procedure involves a toileting schedule modified by the patient's responses and may include techniques for stimulating or inhibiting voiding and complete bladder emptying (similar to bladder retraining). Unlike bladder retraining, habit training can be successful in patients with impaired mental and physical function and is more dependent on the motivation of the staff performing the procedure. It is referred to in the literature as "bladder training," "habit retraining," and "scheduled toileting."

Behavioral modification involves procedures similar to habit training with the addition of positive and negative reinforcers. This technique has been used mainly in children with persistent bedwetting and in chronically mentally impaired patients (37,119).

Carefully controlled studies of training procedures are exceedingly difficult to perform. Several clinical series using training procedures have been reported; however, many have not carefully defined the training procedure, and few have been adequately controlled. Most have involved some type of bladder retraining or habit training for urge incontinence, with 50 to 80 percent of subjects cured or substantially improved (35,48,56, 63,74,82,83,84,95,115,150). Studies that would carefully define training interventions and compare them to other treatments in patients with similar types and degrees of incontinence could lead to better patient selection and more effective treatment.

4.
The Costs and Financing of Incontinence

4.

The Costs and Financing of Incontinence

As a prevalent health problem, urinary incontinence is costly to the health care system, to patients, and to their families. This chapter presents information on the current costs of treating incontinence and the ways in which these costs are met through the health care payment system.

COSTS OF INCONTINENCE

Few studies have systematically examined the costs of incontinence, although some have considered various components of the cost, such as the added costs of labor or supplies used to manage incontinence in long-term care institutions. The U.S. Surgeon General has estimated that $8 billion is spent on incontinence in this country (20); others have estimated that incontinence accounts for up to one-third of the cost of care in geriatric wards in Great Britain (27). The bases for these estimates, however, have not been detailed. The costs of incontinence go far beyond monetary considerations: withdrawal from social activities, psychological distress, burden on family and caregivers, and subsequent predisposition to institutionalization are all important potential effects of incontinence that are difficult to quantify (105).

One report has examined the overall costs of incontinence in nursing homes in this country (111). Several specific assumptions were used to arrive at the cost estimates; however, the figures reported in that study generally concur with the limited data available from the other reports. If only "first-order" costs are considered (i.e., the costs of managing incontinence without the costs of any complicating conditions), in 1983, incontinence added between $3 and $11 to the daily costs of caring for a nursing home patient. The range of costs is accounted for by differing costs of various techniques of management. Blue pads, launderable diapers and bedpads, disposable diapers and catheters were the four methods of management considered in the analysis cited. Of the three components of these costs—labor, laundry, and supplies—the labor involved in managing the incontinent patient was the major contributor.

Interestingly, the first-order costs were calculated to be lowest for patients managed with in-dwelling catheters. However, "second-order" costs (those associated with managing complications of incontinence and its treatment) are highest with in-dwelling catheters because of the high incidence of urinary tract infections associated with this treatment. Although the precise incidence of urinary tract infections requiring specific treatment in chronically catheterized nursing home patients is not known, a conservative estimate of these second-order costs of incontinence is between $2,000 and $3,000 per patient per year. Thus, when one considers total costs, the costs of catheter management are comparable to those of other techniques with lower risks of morbidity. If methods of preventing morbidity from in-dwelling catheters could be developed, such as adding an antibacterial substance to the drainage bag (39,96,143), these devices might then be less costly than other types of incontinence management in the nursing home setting. The National Institute on Aging is currently funding a study addressing these methods (164).

The total costs of incontinence in long-term care institutions may or may not be covered by different sources of third-party reimbursement. In general, although Medicaid reimbursement covers the costs of managing incontinence, nursing homes may have inadequate incentives to care for incontinent patients because they represent a relatively costly condition. Given present fixed reimbursement rates in most States, the first-order costs of incontinence (up to $11 per day) represent close to one-third of the daily per diem for nursing home patients provided by Medicaid (about $37 per day in California). The result is often nurs-

ing home reluctance to accept incontinent patients. The second-order costs, such as the costs of hospitalization to treat skin breakdown and urinary tract infections, are often covered by Medicare or other third-party payers. Thus, the nursing home administrator may be less concerned with these types of costs. However, several States have developed, or are developing, case-mix reimbursement strategies that recognize the increased costs of incontinence (142).

Assuming that there are approximately 600,000 nursing home patients with some degree of urinary incontinence and that in three-quarters of these patients the incontinence is of sufficient severity that catheters or other specific management techniques are used, the yearly costs of incontinence in U.S. nursing homes can be estimated at between $0.5 and $1.5 billion (first-order costs only). This represents between 3 and 8 percent of the total expenditure on nursing home care in this country (111).

The costs of incontinence in the community are much more difficult to estimate. No study has addressed these costs in any detail. Table 4-1 summarizes some of the major direct costs for various approaches to treatment.

Loss of productivity in both those afflicted with incontinence and those caring for the incontinent patient could be substantial. Incontinence can place physical, psychological, and economic burdens on patients and caregivers—costs that are difficult to estimate. In addition, incontinence is

Table 4-1.—Estimated Relative Costs of Treatments for Incontinence (1983)

Treatment	Cost	Components and methods of estimate
Intravaginal electrical stimulator	$ 600[a]	Suggested retail price of device; can also be rented for $95 per month
Artificial sphincter	3,500	Device and surgical fee = $2,300 Four hospital days = 1,200
Periurethral Teflon injection	1,050[a]	Surgical fee = 450 Two hospital days = 600
Silicone-gel prosthesis	3,900[a]	Surgical fee = 2,700 Four hospital days = 1,200
Bladder-neck suspension	3,800[a]	Surgical fee = 2,000 Six hospital days = 1,800
In-dwelling catheter	1,059[a b]	Includes supplies, labor, and laundry (see Ouslander and Kane, 1984)
Disposable pads	2,522[b]	Includes supplies, labor, and laundry
Disposable diapers		
Long-term-care (LTC) institution	1,836[b]	Yearly cost of three diapers per day ("Attends) at $0.75 per diaper
Community	821	
Reusable pads or diapers		
LTC instituttion	1,583[b]	(See Ouslander and Kane, in press.) Yearly cost of four undergarments ("Dignity Pants") at $15 per garment and disposable pads at $1 per day
Community	425	
Drug treatment:		
Urge incontinence		
Ditropan (oxybutinin)	240[a c]	5 mg three times daily
Tofranil (imipramine)	46[a c]	25 mg three times daily
Urispas (flavoxate)	175[a c]	200 mg three times daily
Stress incontinence		
Sudafed (ephedrine)	142[a c]	60 mg three times daily
Premarin (estrogen)		
Vaginal cream	48[a c]	1 g three times weekly
Oral	47[a c]	0.3 mg daily

[a]Does not include the cost of urologic diagnostic evaluation generally necessary before instituting treatment (up to $600).
[b]Minimum estimate of daily cost in a nursing-home setting. Does not include costs of managing secondary complications related to treatment and/or incontinence (Ouslander and Kane).
[c]Cost of a year's supply; includes $2.00 monthly pharmacist's fee.

SOURCE: J. Ouslander, R. Kane, S. Volimer, and M. Menezes, University of California at Los Angeles, 1984.

often cited as a major factor in the decision to institutionalize a dependent person. Although no empirical data precisely define the role of incontinence in precipitating admission to long-term care institutions, certain suggestive data (in addition to the commonly quoted anecdotal information) indicate that incontinence plays a major role in nursing home admission. In one study of stress in caregivers of frail, elderly, community-dwelling persons, difficulties with toileting and incontinence were highly correlated with caregiver burden (105). Most incontinent patients in nursing homes are admitted to the nursing home at a time when they are already incontinent (112). Thus, from the limited data available, it would appear that incontinence is an important factor in the decision to institutionalize dependent persons.

A critical question, and one that has never been systematically addressed, is the potential cost effectiveness of evaluation and specific treatment for incontinence. It appears that few (less than 5 percent) incontinent patients in the nursing home setting have any specific evaluation of their incontinence (112). Although the proportion of incontinent patients that can be completely cured is unknown, many can clearly benefit from an evaluation that identifies treatable conditions; in most instances, this treatment will lead to substantial amelioration of the incontinence. Some experts estimate that one-third of incontinent patients can be completely cured and most others kept dry and comfortable with appropriate management (32,81,174). From a purely economic perspective, even extensive evaluation may be a cost-effective intervention overall (111). Moreover, improvements in the quality of life of incontinent patients and their caregivers likely far outweigh the purely monetary benefits of evaluation and specific treatment for incontinence.

The cost of a typical extensive urologic evaluation for incontinence is approximately $600 (111). The components of such an evaluation include: consultation for history and physical examination ($150); urinalysis and culture ($50); voiding cystourethrogram ($40), cystoscopy ($100); urodynamic tests, including cystometrics, urine flowmetry, and urethral pressure profile ($225); and a followup visit ($35) (111).

However, many treatable conditions can be identified by a much less extensive, less expensive, and less invasive evaluation (87). The role of urodynamic testing in the diagnosis and management of incontinence is especially controversial, particularly in the geriatric population. If properly performed and interpreted, these tests can clearly identify genitourinary conditions that underlie incontinence and that require specific treatment (2,15). However, the testing requires specialized equipment and highly trained personnel, which are available in only a few medical centers; it is relatively expensive and invasive (requiring repeated bladder catheterizations); and it is uncomfortable and inconvenient—especially for frail elderly patients.

Some investigators state that most patients can be properly diagnosed and treated using an algorithmic approach without urodynamics (81); others feel that treating an incontinent patient without urodynamics is like treating a cardiac arrhythmia without an electrocardiogram (32). Because most treatments are used for specific conditions, some type of diagnostic evaluation should be carried out before the treatments are instituted. Identifying the most practical and cost-effective strategies for diagnosing different types of incontinent patients should be a major area of future research.

PAYMENT FOR URINARY INCONTINENCE

Except for services delivered as part of an acute hospitalization, Medicare coverage for incontinence products is quite limited. Part B of the program pays for a prosthetic device that replaces a permanently inoperative internal body organ or function. Thus, sphincters would qualify, but catheters and pants or diapers would not. Medicare's home-health program will permit reimbursement to a home-health agency for supplies ordered by a physician and deemed reasonable

and necessary for the treatment of the patient, but only a small proportion of incontinent persons will be covered by the constrained Medicare home-health benefit, because it is available only to those patients requiring skilled nursing care. Thus, Medicare does not pay for most urinary incontinence pads and pants used outside the hospital.

Medicare will pay for inpatient hospital care associated with incontinence in the same way that it pays for all hospital care. Medicare coverage of acute care hospital costs changed dramatically with the introduction of prospective payment in October 1983 (Public Law 98-21). The prospectively set price per admission does not vary with the use of a given incontinence device, just as it is insensitive to all inpatient services.

Coverage for urinary incontinence products under Medicaid varies from State to State. Coverage is available in such States as New York, California, Florida, Illinois, and Michigan, but not in other States. Even in those States in which Medicaid covers the products, the type and extent of coverage vary considerably. Additionally, the States' requirements for coverage and payments change frequently. In California, for example, disposable diapers, pants, disposable pant liners, disposable underpads, and urinary drainage/irrigation supplies are covered under Medicaid. However, these are subject to requirements such as quantity limitations (two pants per prescription), prior authorization and prescription documentations, and patient age limitations (age 5 or older).

Appendixes

Appendix A.—Incontinence Product Manufacturers: Characteristics and Opinions

This appendix examines the characteristics and opinions of manufacturers of incontinence products. It includes data collected directly from manufacturers of the devices and from various secondary sources such as the Medical Devices Register of the Food and Drug Administration. As would be expected from the wide range of devices available for treatment of incontinence, urinary incontinence products are made by a heterogeneous assortment of firms. Some incontinence products are designed for broad consumer use; others are designed for very discrete types of incontinence, have a high unit cost, and require surgical implantation. Any effort to describe "the incontinence products industry" must recognize this diversity. Two approaches to this dilemma were used: a survey of a representative sample of manufacturers and a more detailed description of a highly specialized product, the artificial sphincter (see app. D).

To facilitate systematic collection of data from manufacturers, a questionnaire was designed and pretested in telephone discussions with a small number of manufacturers. A careful search through various secondary sources, supplemented by discussions with some manufacturers, was used for compiling a list of manufacturers of urinary incontinence products. In all, 48 companies were identified. Most of them were contacted by telephone to seek their consent to participate in this survey. Questionnaires were sent to 38 companies that agreed to respond. Frequent telephone followup was required to obtain an acceptable response rate. Twenty-one companies replied, giving a response rate of approximately 55 percent. A copy of the questionnaire is shown in appendix C. The analysis based on this survey has a number of limitations. The most significant include:

- Potential selection bias among those who responded to the survey. It is possible that companies responding to the survey may have differed significantly and systematically from those not responding. If they did differ, the analysis would suffer from some biases.
- Variations in quality and quantity of responses. Although many of the questions were answered by only a few respondents, the analysis of the importance of the physician's role, the promotional tools used, the relative use of advertising and samples, and the obstacles to growth are based on all 21 responses. The question on barriers to entry was answered by 19 companies (90 percent of respondents). However, the question on proportion of incontinence products purchased by different segments of the population was answered by only 12 companies (57 percent of respondents), and the question on cost of research and development was answered by only 6 companies (28 percent of respondents). The confidence in the analysis of the last two questions is therefore very limited.
- Variations in respondents. The questionnaire may have been completed by people at different levels and positions in the companies surveyed. This could have caused some differences in the perspectives of the respondents.

These survey limitations must be kept in mind while reviewing the analyses in this appendix.

Industry Structure

The substantial size of the incontinence product market appears to have attracted numerous companies into this field. Although it is difficult to pinpoint the exact number, at least 48 companies are involved in the manufacture of one or more incontinence products. A list of these companies is provided in appendix B.

These companies vary dramatically in their size, the number of products manufactured, etc. In many cases, it is virtually impossible to isolate the incontinence component of a much larger corporation. For example, O.M., Inc., employs only seven people and has a total sales volume of $50,000. Proctor & Gamble, on the other hand, employs 25,000 people, and the sales volume of its "Attends" disposable pants was said to be $100 million in 1982. Of these 48 companies, 26 are small (1 to 100 employees), 13 are medium 101 to 1,000 employees), and 9 are large (more than 1,000 employees). Most of the companies manufacture more than one type of incontinence product. The most common combination is pants and pads. Of the 20 companies that manufacture pants, 16 (80 percent) also manufacture pads. Of the 24 companies that manufacture pads, 16 (67 percent) also manufacture pants.

- *Pants*: The disposable and reusable pants market has as many as 20 manufacturers. Despite the number of manufacturers, the market is dominated by a few large companies such as Proctor & Gamble, Bard Home Health, Kimberly-Clark, Dundee, and Whitestone Products. The impressive record of the disposable baby diaper industry in the United States is expected to be dwarfed

by the $6 billion in sales of adult incontinent pants projected by the year 2000 (140).

- *Pads*: Some 24 companies manufacture disposable or reusable pads. Once again, a few large companies dominate: Kendall Co., Bard Home Health, Johnson & Johnson, Dundee, and Whitestone Products.
- *Catheters*: At least 17 companies manufacture either in-dwelling or condom catheters. The large companies in this category are Seamless Hospital Products, American V. Mueller, and Bard Home Health.
- *Electrical Stimulators*: Only two companies manufacture electrical stimulators: Mentor Corporation, a small company in Minneapolis that employs 85 people and Myodynamics, Inc., a privately owned company in Carson, CA.
- *Artificial Sphincters*: American Medical Systems is the leading company for this product, which is described in greater detail in the case history (app. D).

Table A-1 summarizes the companies in the incontinence-product market.

Costs of Research and Development

The amount of time and money spent on research and development (R&D) varies considerably from one product type to another. Accurate information on R&D costs is difficult to obtain from manufacturers, but it is clear that both the time involved and the costs associated with R&D for pads and pants are considerably less than those associated with R&D for the other product types. For example, typical R&D for pads and pants takes about 6 months to 1 year and costs approximately $6,000 to $100,000. For catheters, on the other hand, typical R&D takes 1 to 3 years and costs approximately $100,000 to $500,000.

Other sources of R&D support might come from public funds, such as Government research agencies. The National Institute on Aging has shown recent interest in urinary incontinence and supports research on the topic but has not funded the development of specific devices. The National Center for Health Services Research might be considered a potential source of support for tests of efficacy but has not funded such work in incontinence.

Marketing and Distribution

Companies historically have marketed incontinence products as medical devices rather than as consumer products. Most companies (85 percent) reported on the survey that they use distributors and/or dealers to reach the users. Three companies that do not use distributors or dealers, and three companies that do, sell directly to the users. Thus, only six companies (29 percent) sell directly to users.

Most brands are available throughout the United States; however, some brands are available only in certain regions. Over time, these companies can be expected to begin national distribution. The previous lack of retail distribution, despite the large number of incontinent people in the community, may be attributable to the social stigma attached to incontinence. This situation is changing as new marketing strategies focus on the consumer. The marketing situation has been comparable to that of feminine sanitary products about 40 to 50 years ago. At that time, the subject was not discussed, despite the fact that a huge demand existed for the product. Feminine sanitary products were sold by some pharmacists but were wrapped in plain paper and never displayed. Now these products are commonly sold in supermarkets and advertised on television.

Mail order has become an increasingly effective channel of distribution for many different products in the United States, including urinary incontinence products. Catalog sales of incontinence products by Sears Roebuck and Montgomery Ward, for example, include a wide range of product types and have grown rapidly. This channel of distribution is especially useful for

Table A-1.—Incontinence-Product Industry Structure

Product	Company size: 1-100 employees	101-1,000 employees	1,000 + employees	Total
Pads	11	7	6	24
Pants	10	7	3	20
Catheters	8	5	4	17
Electrical stimulators	1	1		2
Artificial sphincters	1			1
Others	1	2		3

SOURCE: J. Ouslander and R. Kane, University of California at Los Angeles, 1984.

stigmatized products because people can purchase the product without disclosing their problem.

Pricing

Price is one of the important mechanisms used by some companies to capture an increased share of the market. Although one would therefore expect prices to be fairly uniform within a given product type, this is not the case. Some companies have not used pricing as a major tool. Instead, they have opted for product differentiation so that they can charge a different price and consequently have greater sales, greater profitability, or both. This product differentiation is accompanied by considerable price variation, even within a product type. For example, the price of reusable pants sold by Sears Roebuck varies from $7.49 (nylon fabric with vinyl coating) to $8.49 (vinyl brief with cotton-flannel lining) to $10.49 (vinyl coated nylon tricot with cotton-flannel lining).

The typical wholesale price range in 1983 for each product is given below:

Pants:	
Disposable	$0.46 - 0.80 each
Reusable	$7.00 - $14.00 each
Pads:	
Disposable	$0.12 - $ 0.70 each
Reusable	$7.00 - $10.00 each
Catheters	$1.00 - $2.00 each
Intravaginal electrical stimulators	$600.00 each
Artificial sphincters	$2,450 each

Appendix B.—Incontinence Product Manufacturers

American Heyer-Schulte Corp.
American Medical Systems, Inc.
American V. Mueller
Amira Products, Inc.
ATCO Surgical Supports Co., Inc.

Bard Home Health
Bell-Horn

Chaston Medical & Surgical Products
Chesebrough-Pond's Inc.
Coast Clinical Co.

Davol
DiaMed Division
Dri-Pride Division of Weyerhauser
Dundee Professional Health Care
Duro-Med Industries, Inc.

GMG International
Gericare Products
Graham-Field Surgical Co., Inc.
Greenwalk Surgical Co., Inc.

Harvy Surgical Supply Corp.
Hermitage Hospital Products
Hollister, Inc.
HowMedica, Inc.
Humanicare

Inmed Corp.
Intermed Associates, Inc.

Johnson & Johnson Products, Inc.

Kendall Co.
Kimberly-Clark Corp.

Leylor National Hospital Supply Corp.

Mary Clark Products
Mark One Hospital Products
Medical Disposables Co., Inc.
Medical Marketing Group, Inc.
Medicine Industries, Inc.
Mentor Corp.
Minneapolis Society for the Blind, Inc.
Molyncke
Myodynamics, Inc.

O. M., Inc.

Principle Business Enterprises, Inc.
Proctor & Gamble

Rusch, Inc.

Salk, Murray, Inc.
Seamlers Hospital Products Co.
Stanford Professional Products Corp.

TLC Co., Inc.

United Surgical Co.
UroCare Products, Inc.

Wal-Jan Surgical Products, Inc.
Whitestone Products

Appendix C.—Incontinence Product Questionnaire

1. Which of the following urinary incontinence products do you manufacture? (please check) For each, please indicate the year introduced and whether FDA approval is required.

Product	Product Manufactured?	Year Introduced Into Market	FDA Approval Required?
Pants, disposable			
Pants, reusable			
Pads, disposable			
Pads, reusable			
Catheters, simple			
Catheters, condom			
Artificial sphincters			
Stimulators, electrical			
Other (specify)			

2. In what geographical areas do you sell the products?

_____ Across the U.S.

_____ In only some regions of the U.S.

3. What modes of distribution do you use? (check all that apply)

_____ Direct to users

_____ Exclusive distributors

_____ Various distributors

_____ Dealers

_____ Others (specify)

4. Do you have your own salesmen or do you use distributors' salesmen or independent salesmen?

_____ Own salesmen

_____ Distributors' salesmen

_____ Independent salesmen

5. How do you promote the product (check all that apply)

_____ Advertising in professional magazines

_____ Advertising in general magazines

_____ Advertising in newspapers

_____ Advertising on television

_____ Samples

_____ Salesmen

6. What proportion of your product(s) is (are) purchased by nursing homes, private individuals, home-care agencies, Veterans Administration and other institutions?

	Percentage* purchased by			
Product	Nursing Home	Private Individual	Home-Care Agencies	VA and Other Institutions

*Use range if easier

7. What are the list prices of your products?

Product	Price (indicate unit)
	$ per
	$ per

8. To your knowledge, in which States is each of your products covered under Medicaid?

9. What was the cost of research and development and how long did it take to develop each product?

Product	Cost	Time

10. What are the major obstacles to growth of business with respect to these products? (check all that apply)

_____ Competitors

_____ Government policies

_____ Consumer awareness

_____ Cost of product

_____ Inadequate distribution

_____ Other (Specify: _____)

11. Do your products have patents?

_____ All

_____ None

_____ Some (Specify which: _____ _____

_____)

12. What were the company's sales of these products in thousands of dollars:

Product	1977	1978	1979	1980	1981	1982
Pants, disposable						
Pants, reusable						
Pads, disposable						
Pads, reusable						
Catheters, condom						
Artificial sphincters						
Stimulators, electrical						

13. What were the company's sales of these products in thousands of units:

Product	1977	1978	1979	1980	1981	1982
Pants, disposable						
Pants, reusable						
Pads, disposable						
Pads, reusable						
Catheters, condom						
Artificial sphincters						
Stimulators, electrical						

14. What was your market share for each product in the most recent year?
Year_____

Product	Share
Pants, disposable	
Pants, reusable	
Pads, disposable	
Pads, reusable	
Catheters, condom	
Artificial sphincters	
Stimulators, electrical	

15. What do you estimate is the total 1983 market for each of the following product types?

Product	Thousands of Dollars	Thousands of Units
Pants, disposable		
Pants, reusable		
Pads, disposable		
Pads, reusable		
Catheters, condom		
Artificial sphincters		
Stimulators, electrical		

16. What is the role of the physician in determining the product and manufacturers' brand to be used? (check one in each column)

	Product	Manufacturer's Brand
Unimportant		
Moderately important		
Important		
Extremely important		

17. Do government policies affect product development and introduction?

_____ Yes, facilitate development and introduction

_____ Yes, hamper development and introduction

_____ No effect on development and introduction

If you feel government policies facilitate or hamper development and introduction, please explain why:

18. Did your company delay between first considering and finally entering the field of incontinence products?

_____ Yes

_____ No

If yes, what factors were responsible for this hesitation? (check all that apply)

_____ Cost of research and development

_____ Initial costs of start-up

_____ Rate of return

_____ Delays and difficulties getting product approval

_____ Consumer resistance

_____ Physician resistance

_____ Other (specify)

Appendix D.—Artificial Sphincters: A Case Study

This appendix presents a case study of the development of the artificial sphincter, a surgically implantable device designed to treat urinary incontinence. Marketing efforts for this device are directed toward a small group of specialists: urologists. Primary concerns are with performance, success in accomplishing the prosthetic task, and minimizing complications.

The use of artificial sphincters is limited to the few conditions characterized by incompetence of the urinary sphincter. Since the device must be surgically implanted, it is relatively costly to use and its adoption depends on the enthusiasm of physicians, usually urologists.

In 1973, a totally implantable, externally controllable, artificial sphincter was developed by Scott and his colleagues (136). The original idea came from Foley (62), who in 1947 first introduced the concept of external urethral compression using an inflatable cuff. Using a syringe-like mechanism, Foley inflated a cuff around the penis of incontinent males. This device never received widespread acceptance by the medical profession.

The device developed by Scott was made of silicon rubber and marketed by American Medical Systems (Minneapolis) as the AS 721 in the mid-1970s. Unlike Foley's device, this prosthesis could be used in both sexes and the cuff was surgically implanted to surround the urethra. The reservoir used to inflate the cuff was placed in the abdominal cavity. The two pumping mechanisms, implanted in the scrotum in males and the labia in females, were inflated and deflated by the patient. Each pumping mechanism consisted of a bulb and two valves. The valves controlled the direction of fluid flow inside the prosthesis and were designed to set the precise cuff pressure. The B4 valve was critical to controlling the pressure applied to the urethra. The valve ensured that regardless of the number of times the inflating bulb was squeezed, the cuff could reach a predetermined pressure equilibrium but avoid high, potentially harmful pressures.

The major problem with the AS 721 was valve failure. To increase mechanical reliability of the system, Model AS 761 was introduced in 1976. AS 761 eliminated the critical dependence on the valve through a pressure-regulating balloon. However, after testing the device, the Balloon Sphincter Clinical Study Group (10) found that 50 percent of the failures resulted from mechanical complications, so production was stopped.

The next model, AS 742, differed substantially from the previous devices. Rather than requiring manual inflation, the cuff of the newer model automatically inflated by fluid forced through a resistor set at a controlled rate by a pressure-regulating balloon. As a result, the patient operated only a deflating bulb. Results have shown a higher success rate (70 versus 50 percent) and fewer mechanical failures with this than with previous models. In addition, the device has been easier to implant and simpler to operate. The success of the AS 742 has depended on a balloon that maintains a low-pressure reservoir. High pressures around the urethra have been the main causes of urethral erosion, a very serious and often irreversible complication of sphincter implantation. The low-pressure balloon reservoir has reduced the number or urethral erosions but has not eliminated them completely. A major problem with the AS 742 has been the requirement that the cuff be inflated while tissue was healing in the immediate period after implantation.

Primary deactivation is a newer technique designed to reduce the rate of urethral erosion. With primary deactivation, the cuff is kept deflated after the sphincter is inserted, allowing the tissues to heal after the operation. The sphincter is activated several weeks later. Thus the newer sphincters (AS 791/792) resolve the problem of maintaining constant pressure under all circumstances with the AS 742 and are especially useful for high-risk patients (those who already have weak tissues from prior surgical procedures).

The most recent sphincter developed by American Medical Systems (AMS Sphincter 800TM) allows the initial activation of the device to be carried out without a second surgical procedure (which is sometimes necessary for AS 791/792). Studies of this new model have not been published in the medical literature.

Studies of the older models have shown a 40 to 85 percent success rate (see above and table 3-1). According to data presented in a marketing brochure published by American Medical Systems, 4,000 children and adults have been helped by their artificial sphincters since they were first produced in 1972. Their data on the 486 implants of model AS 791/792 indicate that 74 percent were implanted in males; 32 percent in patients aged 20 or younger, 35 percent in patients aged 21 to 60; and 32 percent in patients older than 60. Thirty-five percent of these sphincters were implanted for post-prostate surgery (radical prostatectomy, 19 percent, and transurethral resection, 16 percent); 26 percent for myelomeningocele; 9 percent for spinal cord injuries; and the remainder for a miscellaneous group of conditions (generally involving neurologic abnormalities) (4).

An alternative sphincter was developed by Michael Rosen (128). This device was also made of silicon rubber and has a three-armed clamp that fits across the

urethra. One arm carries a balloon attached to a saline-filled reservoir bulb (positioned in the scrotum) and a release bulb. Compressing the reservoir bulb inflates the balloon, which partially increases the urethral resistance to maintain continence. To void, the release valve is pressed, which deflates the balloon. The advantages of this device are its relative simplicity, lack of circumferential compression, and the relatively short urethral dissection needed to implant the device.

Clinical studies in approximately 60 male patients demonstrated a 50 to 75 percent success rate (table 3-1), but some of the patients required more than one operation. Failures were most commonly caused by mechanical malfunction and infection. The longest functioning prosthesis lasted 26 months.

In summary, the artificial sphincter appears to be a treatment option for those patients with severe urinary incontinence caused by dysfunction of the bladder outlet and/or urethral closure mechanisms. This would include young patients with neurological disorders (e.g., myelomeningocele), women with stress incontinence who have not been helped by standard surgical correction procedures, and men with post-prostatectomy incontinence from sphincter damage. Thus, patients who are appropriate candidates for sphincters represent only a small proportion of the incontinent population. Improved mechanical properties of the sphincters and techniques of surgical implantation are likely to increase the success rate and diminish complications of these devices (75).

Appendix E.—Glossary of Terms

Acute incontinence: The sudden onset of episodes of involuntary loss of urine. Usually associated with an acute illness or environmental factors that impair the mental or physical ability of the patient to reach a toilet or toilet substitute on time.

Alorithmic approach: In incontinence testing, a step-by-step procedure used to diagnose incontinence.

Bladder neck suspension: An operation performed on women with stress incontinence in which the bladder neck and urethra are repositioned; the most common surgical procedure for incontinence.

Case-mix reimbursement: A hospital and nursing home payment plan which considers both the relative frequency of admissions of various types of patients and the severity of their condition.

Catheterization: With respect to the urinary system, the passage of a small tubular instrument into the bladder for the purpose of urinary management.

Cholinergic drugs: Drugs which are activated by choline and associated with the synaptic transmission of nerve impulses; promotes bladder contraction.

Diabetic neuropathic bladder: A functional disturbance of the bladder which can be found among persons with diabetes; marked by the bladder's poor ability to contract.

Established incontinence: Repeated episodes of involuntary loss of urine not associated with an acute condition.

External catheterization: With regard to urinary functions, a catheter applied to the penis; requires frequent changing and may result in local skin irritations or other complications.

Fecal incontinence: Involuntary excretion of stool sufficient in frequency to be a social or health problem. Relatively uncommon in community-dwelling persons, but more prevalant among persons in nursing homes.

First-order costs: Costs assessed without consideration of complicating conditions. With regard to incontinence, the immediate costs of labor, laundry, and supplies.

Functional incontinence: Leakage of urine caused by chronic impairments of either mobility or mental function, marked by the inability or unwillingness of the patient to toilet himself or herself independently and a lack of sufficient help with this task.

Iatrogenic factors: Aspects of the attending physician's activity which inadvertently result in an adverse condition for the patient.

In-dwelling catheter: With respect to the urinary system, a catheter that is held in position in the bladder by a device resembling an inflated balloon. Infectious complications may arise with long-term use.

Intermittent catheter: A catheter which may be inserted at regular intervals; use by selected patients may prevent risks of infections associated with the in-dwelling catheter.

Kegel excercises: A series of repetitive contractions of muscles of the pelvis and vaginal wall for the purpose of vaginal health; also used in the management of stress incontinence in females.

Nosocomial infections: Infections which originate in a hospital or institution.

Overflow incontinence: Leakage of small amounts of urine caused by anatomic obstruction to bladder emptying and/or inability of the bladder to contract.

Palliative treatments: Treatment designed to provide relief from a condition, but not to cure that condition.

Pessary: A donut-shaped piece of inert material inserted into the vagina to support the bladder outlet in women with stress incontinence.

Placebo effect: An improvement in condition that occurs in response to treatment, but cannot be considered a result of the specific treatment used.

Prophylactic antibiotic therapy: Therapy designed to ward off disease through the use of antibiotics taken in a preventative manner.

Prostatic hyperplasia: The abnormal multiplication in the number of normal cells in normal arrangement in the prostate gland.

Sham operation: An operation which the patient believes was performed, but actually was not performed for the purpose of creating a control group for experimenal measure.

Sphincter: In the genitourinary system, the ringlike band of muscular fibers around the urethra that through its constriction regulates the flow of urine.

Stress incontinence: Leakage of urine, either in small or large amounts, as intra-abdominal pressure increases.

Urge incontinence: Leakage of varying amounts of urine because of the inability to delay voiding long enough to reach a toilet or toilet substitute. Can be caused by a variety of genitourinary and neurologic disorders.

Urinary incontinence: An involuntary loss of urine sufficient in quantity and/or frequency to be a social or health problem.

Urodynamic testing: Testing which pertains to the flow and motion of urine in the urinary tract.

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